National Conference
on
Interstate Milk Shipments (NCIMS)

Evaluation of the
NCIMS HACCP Pilot Program
Phase II Expansion
April 17, 2003

Table of Contents

NCIMS HACCP Committee Membership

- Claudia Coles – Chairperson, State of Washington
- Paul Hoge – State of Pennsylvania
- John Beers – State of Virginia
- Susan Esser – State of Michigan
- Richard Graham – State of Louisiana
- Dave Robbins – Dean Foods
- Rob Byrne - NMPF
- Chris Newcomer – New-Tech Consulting, Inc*
- Bill Sveum - Kraft
- Paul Dersam - Upstate Milk Coop.
- John Rushing - N.C. State University
- Allen Sayler - IDFA
- Rebecca Piston - Garelick*
- Steve Sims* - FDA MST CFSAN
- Randy Arbaugh* - FDA DFSR ORA
- Steve Pierson* - FDA RMS ORA

*Technical Advisors

Plants Participating in Phase I & II of the NCIMS HACCP Pilot

Connecticut
Yofarm*

Florida
Publix

Maine
Garelick (Deans)
Oakhurst*

Michigan
Michigan Milk (Phase I only)

New Jersey
Tropical Cheese
Parmalat*

Pennsylvania
Meadowbrook*
Dutch Valley*

Utah
Gossner
Dannon**

Vermont
St. Alban's

Washington
Safeway
Wilcox*

* Phase II Plants only

EXECUTIVE SUMMARY

Background:

The 1997 National Conference on Interstate Milk Shipments (NCIMS) appointed a committee to address how a voluntary HACCP System should be implemented, evaluated, monitored and enforced under the National Conference on Interstate Milk Shipments (NCIMS) as an alternative to the traditional Inspection/Rating/Check Rating System. This program will:

- Utilize current National Advisory Committee on Microbiological Criteria for Foods (NACMCF) HACCP principles consistent with current FDA HACCP recommendations.
- Continue to assure at least the same level of milk safety provided by the traditional Inspection/Rating/Check Rating System.
- Continue to provide uniformity and reciprocity under the HACCP alternative to the traditional Inspection/ Rating/Check Rating System.

The 1999 NCIMS Conference authorized the committee to conduct a voluntary pilot study to evaluate the proposed plan. The study was conducted in six plants from different states and FDA regions. The plants were chosen to represent a range of plant sizes and product mixes. Sites were selected from volunteer plants with state regulatory approval.

Phase I Evaluation Team
An Evaluation Team, composed of members from state regulatory, industry, FDA and academia, visited all six pilot sites during the summer and fall of 2000. The team presented questionnaires to plant management and personnel, state regulators, listing officers, Grade A milk program directors, and Regional Milk Specialists prior to onsite visits, then conducted follow-up interviews onsite when possible, to evaluate the development, implementation, and maintenance of the pilot program.

On-site visits included an extensive review of the HACCP plant's records as well as a comprehensive evaluation of the plant's facilities, equipment, operation and implementation of the HACCP system. State's regulatory system was evaluated. These were used to evaluate the pilot first-hand at the participating plant location and at the regulatory agency offices. The result was a report to the NCIMS HACCP Committee.

The HACCP Committee made changes to the HACCP system as a result of information gathered from the pilot. The voting delegates at the 2001 NCIMS Conference voted to continue the pilot until the 2003 Conference and to authorize the inclusion of additional plants in the study.

Phase II Evaluation Team
The Phase II Evaluation Team activities were patterned after Phase I and included the use of questionnaires to industry and regulatory personnel and on-site visits at the five continuing Phase I and the three new Phase II plants listed at the time of the Evaluation Team visit. These visits included seven states. On-site activities included review of plant facilities, extensive reviews of HACCP records, plant employee and regulatory personnel interviews and evaluation of state regulatory systems, including records.

Responses to questionnaires for industry, state regulators, and FDA Regional Milk Specialists showed that these groups generally considered the level of food safety under the pilot to be at least equivalent to that provided under the traditional system. Under the conditions of the pilot, the Evaluation Team found the level of food safety under the pilot to be at least equivalent to that provided under the traditional system based on information obtained from survey responses, a comparison of inspections made under the traditional system with state HACCP audit reports, regulatory sample reports, and review of regulatory enforcement action records

The Evaluation Team found areas in the pilot document needing further clarification and modification, including the need for a standardization program for HACCP listing officers and improved training of all participants. This report contains the Evaluation Team's recommendations for these clarifications and modifications, which the Evaluation Team believes, if implemented, will result in the capability to uniformly apply a voluntary alternative HACCP program in a manner equivalent to the traditional NCIMS program and that will form an adequate basis for reciprocity between states that will continue to assure at least the same level of milk safety provided by the traditional Inspection/Rating/Check Rating System.

Technical Resource Team
In order to provide uniform interpretation of the pilot, and to answer technical questions arising from the pilot, a Technical Resource Team consisting of NCIMS HACCP Committee members from state regulatory, industry and FDA was formed. The team functioned effectively throughout the pilot and communicated its decisions utilizing the FDA web site. The Evaluation Team recommends that this Technical Resource Team continue at least through the implementation phase of a voluntary alternative HACCP program.

Summary of Findings
Resources were found to be an issue for both industry and regulatory agencies. The authority to provide these resources pre-supposes industry and state regulatory upper management commitment.

Industry resources that were needed included technical expertise, training, and supervisory oversight. Time was necessary for outside training of key technical personnel and in-house training of team members, supervisors and operators. Further time commitments were required to develop, implement and maintain the program. Documentation and verification of the applied program required the time of a

coordinator. Due to the demands of the pilot schedule, program development and in-plant training was rushed in Phase I, but the time frame for implementation was not prescribed in Phase II.

It was necessary for the regulatory agency to commit the personnel resources normally required for the plant inspection effort, plus additional time for training of regulators and listing officers in the basics of HACCP and auditing. Increased communications with the plant and extra visits were necessary in the development and implementation phases. The team found that time spent on the audit will take longer than the traditional inspection time, at least until the auditor becomes comfortable and familiar with the plant's system.

The training that was provided for the pilot program was adequate for the start-up of the pilot, however additional training will be necessary to implement the proposed program. The pilot study pointed out areas of need for increased training emphasis. There was confusion among the participants about the relative difference between the prerequisite program, associated SSOPs and the CCPs. In Phase II, the HACCP committee retitled "SSOPs" as "mandatory Prerequisite Programs". Participants requested more "hands-on" training and more guidance in the technical aspects of hazards identification, control and verification. In response to this concern, the Evaluation Team has recommended the development of a Hazards and Controls Guide*, and made specific recommendations to the HACCP Committee Training Team to provide enhanced training in auditing techniques.

The majority of recommendations from the evaluation team deal with the issues of training, auditing and oversight. Some regulators perceived the HACCP pilot system to be more subjective and less prescriptive than the traditional NCIMS program. This issue was acknowledged as a problem under Phase I. Modifications under Phase II helped minimize this problem by developing audit training, critical listing elements and further clarification of the audit form and HACCP documents. This report contains recommendations that we believe, will adequately address this issue.

Industry responses to questionnaires reflect the positive impact of implementing HACCP in their facility, noting the improvements in plant sanitation, corrective action programs, and reductions in withheld finished product. Industry comments indicated that operators were more cautious and thorough due to more training. Implementation of the HACCP pilot program resulted in a significant improvement in allergen management.

The Evaluation Team observed that roles and coordination are somewhat different

* Since HACCP is science-based, members of the HACCP Team must have available adequate technical resources to assist in the identification of hazards, choosing controls, and system verification. In order to provide assistance in conducting the hazard analysis and developing the rest of the plan, the Evaluation Team recommends the development of a "Hazards and Controls Guide" and models of HACCP plans. The Evaluation Team also recommends that a model prerequisite program as well as guidelines for the implementation of required PPs should be developed and made available for use in future training.

under HACCP and may change as the program matures and more experiences are gained. This is necessary to effectively implement HACCP program after the pilot. The team found that the relationships between industry, state regulators and FDA Regional Milk Specialists in most cases, reported to be positive.

Conclusions

The evaluation team recommends that the NCIMS HACCP Committee should modify the pilot document incorporating the team's interim findings and recommendations. The committee should produce a proposal that recommends the NCIMS implement HACCP as a voluntary alternative to the traditional NCIMS program. This document represents the final report to be presented to the NCIMS HACCP Committee.

REPORT OF THE EVALUATION TEAM:
Introduction

The Evaluation Team was charged with compiling data and observations from many sources, carefully considering these data in light of what was found during plant and state regulatory visits, and producing findings for the evaluation. The following report is compiled from information collected by the evaluation team with the assistance of industry and regulatory personnel. The evaluation team made onsite visits to all the participating listed HACCP pilot plants and their state regulatory agencies. Personnel interviews, regulatory records and questionnaires from these participants and from FDA, were also used. Specific observations were made from plant and state regulatory visits and these were also recorded for compilation of the Evaluation Report.

To prepare this report, the team evaluated the observations to produce findings that had widespread relevance to implementation and maintenance of the pilot program. In some instances, an observation made in only one or two plants was considered to be of such general interest or importance that it was incorporated into the findings. Also note that some individual observations did not rise to the level of general concern or were determined not to be relevant to the study at hand and, therefore, do not appear in findings that result in recommendations.

Recommendations primarily take the form of changes or clarifications to the pilot program. In some cases, the recommendations may address ancillary programs to the official documents, such as training issues and model guidance for the evaluation of hazards and production of the complete HACCP system.

A word of caution to the reader is appropriate. These general findings and recommendations represent the consensus of the evaluation team's deliberations. Much of the raw data and observations collected by the Evaluation Team are presented in the attached documents to substantiate the general findings of the Evaluation Team. These initial observations are very site and date specific. Many of these are individual team member's observations and may not represent the judgment of all who participated in the evaluation. Individual's observations were sometimes captured for further discussion and later evaluation by the complete evaluation team.

As a final word to those who may review this report, the recommendations are those of the NCIMS Evaluation Team. They were drafted for the purpose of presentation to the full NCIMS HACCP Committee. The NCIMS HACCP Committee membership is broad-based and is directly charged with the responsibility for making changes to the NCIMS HACCP program.

The sections of the report correspond to those sections found in the NCIMS Phase II Pilot document (for details of the Phase II Pilot document, see www.cfsan.fda.gov/~comm/daipilo2.html)

Definitions

Recommendations

1. Remove the definition of "control point" from the definitions to be inserted into the PMO (See PMO Changes other that Appendix K).
2. Add the term, "potential hazard" to the Definitions section (See PMO Changes other that Appendix K).
3. Enhance the definition of "control measure" to emphasize that control measures are used at a CCP (see PMO Changes).
4. Request the NCIMS HACCP Training Subcommittee include examples that clarify PP#3 (Prevention of Cross Contamination) and PP#5 (Prevention of Adulteration) for use in future training.
5. Instruct the Training Subcommittee to emphasize the concept that PP's can only reduce the likelihood of occurrence of a hazard. Only a CCP can be used to control a hazard.

Findings

The definitions used in the Phase II program come substantially from the 21CFR120, the juice HACCP regulations, and are mainly from the NACMCF recommendations.

1. "Control point" is an archaic term whose concepts have been commonly replaced by the terms "SSOPs," and in our case "PPs."
2. There was some confusion in using the terms "potential hazard", "control point" and "control measures."
3. Plants exhibited some confusion between the terms "adulteration" and "cross contamination" since no definitions were provided.

Observations: Note **-** These observations are very site and date specific, representing individual team member's observations. Individual observations were captured for further discussion and later evaluation by the complete Evaluation Team. Many of the observations are based on requirements listed in the plant's HACCP written program and are not requirements of the NCIMS HACCP pilot program.

1. It is important to understand that hazards are not to be controlled by prerequisite programs. Prerequisite programs can reduce severity or likelihood of occurrence of a potential hazard, but not control it.
2. Note to the definitions section – include, fix or remove "potential hazard", "control point", "control", "prerequisite programs", "control measures".
3. NCIMS Committee must do a better job of clarifying differences between Adulteration and Cross Contamination. Many items in the Cross Contamination prerequisite are really Adulteration.

Implementation of the Hazard Analysis Critical Control Point (HACCP) System

Recommendations

1. Modify the requirements for listing a plant under HACCP to require the plant to have a minimum of 60 days of records prior to a listing audit. (see Methods modifications)
2. Require a state HACCP audit prior to the listing audit. (see Procedures document).
3. Modify the pilot document prior to incorporating it into Appendix K to include a brief paragraph in the "Background," or other appropriate section, to address the need for industry senior management support in terms of personnel time and resources in order to implement HACCP successfully.
4. The HACCP committee should produce a Hazards and Controls Guide. The HACCP Committee should recommend that FDA issue this under the M-I system.
5. The Training Subcommittee be instructed to emphasize the need to keep the components of the plan unencumbered by other programs not directly relevant to the HACCP effort so the system is manageable and can be efficiently verified and audited.
6. The Training Committee should develop training materials on all mandatory prerequisite programs and a model hazard analysis for common Grade A products.

Findings

Implementation was found to be the most time-consuming and difficult part of the HACCP pilot. It uses considerable resources from both the plant and the regulatory agency.

1. Most states in the Phase I pilot felt pressure to get plants listed according to schedule so the pilot could proceed. In Phase II, it was made clear that there was no pressure to get the plants listed if they were not ready. The question of when the plants were ready was usually answered in terms of operating under the fully implemented plan for a specified period of time (usually mentioned as 60 to 90 days) and having records to document monitoring.
2. The Evaluation Team found that the success of implementation depended on management decision, declaration of intent and provision of resources—technical, supervisory, and clerical. It was important that the program had a champion, but sole dependence on a single person such as the QC director made implementation and maintenance difficult in all but the most centralized management systems.
3. Plants and states often remarked that they did not have enough guidance and would appreciate a hazard guide and examples of acceptable PPs, HACCP plan and related documents.
4. Conversion from the Phase I to the Phase II requirements caused challenges for plants. In some cases, plants did not give updating of the HACCP program priority. Because of this there were inconsistencies in documentation and practice.
5. Some plants had difficulty meshing their corporate QC plan with the requirements of the HACCP pilot, resulting in confusing documentation and procedures. This usually resulted in complicated programs that were difficult to verify and audit.

Observations Note - These observations are very site and date specific, representing individual team member's observations. Individual observations were captured for further discussion and later evaluation by the complete Evaluation Team. Many of the observations are based on requirements listed in the plant's HACCP written program and are not requirements of the NCIMS HACCP pilot program.

1. Problem with HACCP team not being very functional. Dependent on single person. Meetings are not frequent or fully attended. HACCP Coordinator seems to be in traditional role of quality control that does not involve other HACCP team members.

2. The Evaluation Team found a very modern, well-equipped and well maintained plant, with an enthusiastic, committed workforce, dedicated management and a mature HACCP system. The plant has experienced a stable workforce during the last year that has contributed to their ability to maintain and upgrade their HACCP program. It has also contributed to a better-trained staff.

3. The HACCP Committee should establish one set of reporting forms and charts to improve uniformity between HACCP plants and state enforcement efforts.

4. The continuous updating of the written HACCP program has resulted in some inconsistencies in the HACCP document:

   a) Use of names for prerequisite programs in the table of contents, hazard analysis and in specific prerequisites.

   b) The prerequisite for equipment sanitary design requires 3-A construction but woven material belt, rough welds and exposed bolts in cottage cheese equipment does not meet this requirement.

   c) Entering of information on the Hazard Analysis form (i.e. eggnog, blending step, air blows used to move product throughout the plant, use of a metal detector for plastic lidded cottage cheese cups but not for foil-lined cottage cheese cups, fortified skim milk) including identifying specific prerequisites for reducing the likelihood of a hazard.

   d) Hazard analysis entries for staph. toxin development did not support likelihood of a hazard.

   e) Documentation

   f) Verification

5. The Evaluation Team continues to find that the resources needed in order to develop and maintain the HACCP program are significant. Once the HACCP plan design has been completed, fully implemented and functioning for a reasonable amount of time, the team believes that resource requirements will be reduced.

Prerequisite Programs

Recommendations

1. Modify the pilot document prior to incorporating it into Appendix K to deal with general-purpose PP's such Building, Premises, Construction and Maintenance (see Appendix K).
2. Modify the pilot document prior to incorporating it into Appendix K to show in the written prerequisite programs what is to be monitored and list the frequency of monitoring. All other details related to written prerequisites should be addressed through training programs (see Appendix K).
3. Modify the pilot document prior to incorporating it into Appendix K to provide details and guidance language which is needed in each of the eight mandatory prerequisites including (see Appendix K):
    a. Guidance that the mandatory prerequisite on Pest Control shall include construction and maintenance of premises (floors, walls, ceilings, doors, windows, etc.).
    b. Addressing both employee health and exposure to high-risk situations as requirements to be addressed in the mandatory prerequisite on Employee Health.
4. By the HACCP Committee's acceptance of this report, the Training Subcommittee shall revise the section on Prerequisite Programs in the Dairy HACCP Core Curriculum to emphasize content, format and procedures in developing PP's. The importance of monitoring procedures and review should be emphasized. Each PP shall be self-contained with all individual procedures documented.
5. The Evaluation Team recommends additional consistent terminology under "Records", a centralized list of records, and dates for version numbers should also be applied to PP's (see Appendix K).
6. By the HACCP Committee's acceptance of this report, the Training Subcommittee shall under "Implementation" train that the HACCP written program be unencumbered by corporate QC plans and other quality systems should be emphasized in training.
7. By the HACCP Committee's acceptance of this report, the Training Subcommittee shall, emphasize that PP's need documentation of corrections.
8. The Evaluation Team recommends that an audit insure that the written prerequisites are adequately implemented, monitored, audited and documented and this recommendation be incorporated into Appendix K (see Appendix K).
9. The non-critical limit parameters, i.e. differential pressures, that were originally managed as PP's for pasteurization shall be included in the Pasteurization Model under verification as calibration of equipment (see Appendix K and PMO changes).
10. Modify the pilot document prior to incorporating it into Appendix K, to require prerequisites identified in the hazard analysis that reduce the likelihood of occurrence of a potential hazard to be written, monitored, audited and documented as in the case of other required PP's (see Appendix K).

Findings

Prerequisite programs design and implementation were probably the result of more observations than any other category. The following general comments can be made based on the observations:

1. Plants were inconsistent in the breadth of their PP's. The Phase I pilot recommended PP's in several categories. For the Phase II pilot, the emphasis was placed on the 8 SSOPs required by the juice HACCP regulations along with those PPs which were used to justify that an identified potential hazard was not likely to occur. Some plants did not address general-purpose PP's such Building, Premises, Construction and Maintenance or Training.
2. Without clear guidance from the pilot, plants had some difficulty understanding which procedures to include in prerequisite programs.
3. Several plant personnel noted that models of appropriate PP's would be useful in deciding what a typical PP should look like and what should be included in each PP.
4. Plants were inconsistent in the depth of their PP's. They varied considerably in level of detail. Some may still have too much material not related to sanitation and safety, making extra work for the plant and the auditors. Prerequisite programs should identify the goals, the personnel responsible, and those procedures designed for accomplishing the goals, along with documents used for records of monitoring and correction. Frequency of monitoring was an issue in some situations.
5. Implementation of PP's was not consistent between plants. Some followed the programs carefully while some used the programs more as guidelines. There were numerous instances where PP's were too general or referred to a general section of the PMO or a corporate policy. Several plants had PP's that were inconsistent with their practices, or in some cases procedures had been changed without changing the PP.
6. PP documents were sometimes difficult to access for the auditor because of inconsistent terminology between the HA and the PP. A list of associated documents would have been helpful.
7. The committee noted that there was no method of tracking repeat occurrences of noncompliance in the prerequisite program that could be used for verification.
8. There seemed to be a need to improve verification of documents as well as verification of PP's as a whole. Verification should identify inconsistencies and other shortcomings.
9. Pasteurization equipment and operation requirements were scattered among several different PP's in some plants, making the pasteurization CCP difficult to verify.
10. Those items which deal with proper installation and design of equipment and construction items such as plumbing and cross connections often have not found a home in PP's. Some plants have handled these things using a plant audit checklist.
11. In the case of corrections required by most of the prerequisite programs that were product-related, most were accomplished.

12. Corrections to general sanitation related prerequisites such as pest control and monthly audit checklists were not well tracked, and often, repeated noncompliance was noted.
13. In those places where corrections could not be accomplished immediately there often was no mechanism in place, such as a corrections log and timetable to encourage follow- up.
14. The Phase II HACCP pilot document does not specifically mention prerequisites identified in the hazard analysis that reduce the likelihood of occurrence of a potential hazard as having to be written, monitored, verified and documented similar to the eight mandatory prerequisites.

Observations Note - These observations are very site and date specific, representing individual team member's observations. Individual observations were captured for further discussion and later evaluation by the complete Evaluation Team. Many of the observations are based on requirements listed in the plant's HACCP written program and are not requirements of the NCIMS HACCP pilot program.

1. Transport vehicle inspection program referenced in prerequisite program but assigned individual not checking transports (example, 4 transports at loading dock with 3 dirty, but checklist filled out showing all were clean).
2. Overall, the PP are some of the best we have seen, in particular PP #2 on Cleaning and Sanitizing of equipment such as specifying visual inspection monitoring, chemical strength monitoring, frequency of cleaning, broken down by type of equipment, very detailed.
3. Instructions for operation of COP tank in the prerequisite program states "heat up to 150 degrees"; however the steam controls are not working very well and there is no thermometer. The temperature was found to be 120 degrees. How does the plant monitor temperature, length of wash, equipment washed, etc.?
4. Plant lists quarterly micro. analysis in PP to control microbial hazards in caps, jugs and cartons, but they do not do this.
5. Plant does not appear to have incorporated the overall concept of HACCP into their operational culture.
6. Documents were inconsistent between corporate SSOPs and the written PP's such as, safety of water PP for analysis noted in different documents as annually, twice a year, or quarterly. Need to have consistency.
7. Some documents are not specific enough to monitor and verify the program such as the requirement for safety of water. PP says that it must be analyzed to confirm potability but does not indicate what it should be analyzed for and at what frequency, etc.
8. Recirculated water is noted in the PP to be treated and monitored. Information needed on treated with what, how often, and what are limits.

9. Condition and cleanliness of equipment states that environmental testing for pathogens is to be done on a routine basis. What does this mean? Provide more detail.
10. Prevention of cross contamination prerequisite does not address pressure differential calibration for the two HTST pasteurizers as per pasteurization model.
11. Protection from Adulteration – to find all the things to be covered under this PP, you have to go to three separate ones, “Building interior”, “Design and Installation”, “Sanitation”.
12. The mandated eight required prerequisites are difficult to identify within the complete PP. This results in difficulty in following because they are contained in other general PPs. Lack of a required PP on cross connection are difficult to find (condition and cleanliness of food contact surfaces is in three different places, one called “Food contact surfaces”, “Sanitation” and “Design and Installation”.
13. Recommend to NCIMS committee that the 8 required PPs should be written separately from the rest of the PPs.
14. Transportation and Storage PP does not address that source of milk must originate from a listed source.
15. Potential cross connection between raw and pasteurized lines in valve cluster in blending area. Need physical break
16. The prerequisite for Transportation and Storage mention temperature control for ingredients but gave no criteria for temperature control of finished product
17. Prerequisite for Equipment did not cover cross connections between raw and pasteurized (one was noted in the plant). This PP included calibration of equipment but the Evaluation Team noted that cheese dressing tank thermometer was inaccurate.
18. The prerequisite on Premise states boiler chemicals meet EPA/USDA approval but did not cite CFR even though culinary steam is used for direct injection into cottage cheese.
19. The prerequisite on personnel and employee health did not address high risk disease situations, i.e. visiting daycare centers, attendance at church dinners, contact with individuals with food borne infectious disease such as TB, etc.
20. There is a need to designate or define what are “toxic” materials to differentiate them from non-toxic materials in the Transportation and Storage prerequisite.
21. Quarterly microbiological analysis records on non-food products were not available and appear not to exist as per the Transportation and Storage prerequisite. The terms, “When possible” or “Where necessary” is used frequently in the prerequisite program description. This is a weak, non-committal statement that does not provide consistent control of a prerequisite and should be eliminated.
22. The write-up of the prerequisites tends to be very general and does lead to uncertainty regarding the coverage and details of prerequisite management.

23. The hazard analysis on Equipment addresses all equipment, but equipment maintenance for separators and homogenizers not mentioned.
24. Finished product storage and finished product are monitored for temperature daily according to the prerequisite but records only address product and not storage area.
25. Flow diagrams are not required by the pilot program document to be present, accurate, and verifiable.
26. Preliminary steps are not mentioned in the document.
27. The floor in the pasteurizer area is in poor repair: Note the “Premises-plant construction PP” has been withdrawn.
28. Pathogen growth at the Finished Product Storage and Transportation steps is identified as a hazard for a number of products by the Transportation and Storage prerequisite but control measures do not specifically address.
29. The use of a corporate Food Safety Audit form performed every 2 periods (every 28 days) is too infrequent for some activities to use this document as the sole record to support control under a prerequisite program. Tailor form so more specific to plant activities and necessary monitoring frequency.
30. The PP program does not address all issues identified in the HA and also does not identify specific records. Appears the PP was driven more by need for consistency with the monthly Corporate Food Safety audit form than on developing the mandatory prerequisites as detailed under the NCIMS HACCP pilot program.
31. The prerequisite on Equipment under Food Contact Surfaces addresses rust on the outside of equipment. What is the relationship to food safety?
32. All equipment is maintained to insure that there is not chemical or physical hazard that will affect food safety. Unsure what was intended to cover cross connections, metal fragments, protection of openings, etc.
33. Prerequisites do not reference these records.
34. The plant’s prerequisite program needs to control all conditions that contribute to overall product safety. Some examples of deficiencies are:
    a) Air under pressure is not addressed even though plant was monitoring it and had supporting records.
    b) Silo tank wash frequency is not addressed with specificity, i.e. frequency was referenced as “daily” or “as used” but actually practice is a maximum of every 72 hours.
    c) Details regarding manual cleaning of equipment are not completely described in the Cleaning and Sanitizing prerequisite even though the plant does monitor and document this activity.
    d) The cross connection prerequisite focused on regenerator pressures only and did not address piping connections. The Team found a cross connection at batch tank #1.
    e) The water prerequisite for boiler water required current boiler water letters, but letters on file are very dated (10 years old).

f) The prerequisite for Protection from Contamination does not address re-work (included only a temperature reference).
g) Supplier's letters of guarantee are outdated (up to 10 years old). Additionally, certificates of analysis and supplier guarantees need to be verified.
h) The prerequisite on adulteration did not address allergens.
i) The prerequisite on incoming ingredients required certificates of analysis but there were no specifications or details indicated.
j) Find a way to include GMPs

35. Monitoring is very good on the PP. Some gaps particularly in premises, surroundings, flies.
36. PP general comment: Prefer the PP would use name or reference number to aid in finding the document.
37. A document list would be helpful.
38. In a plant this old recommend that an additional PP for construction, housekeeping, facilities, and premises be included.
39. Monthly walk through is still being used, but no longer using a checklist. If there are standards given for the criteria, it is not mentioned
40. An outside contractor is handling the pest control. Plant Management reviews report, does follow up, and approves the report.
41. It is not clear what the reference to the PMO meant in terms of the PP requirements for the plant
42. PP's for premises-- grounds, plant construction, recalls and training, were withdrawn by the plant. We were unsure why
43. What is the FDA illness form mentioned on the rating—Food code.
44. Use of the PMO references---what do they bind the plant to?
45. COP records are well documented and log used to track concentrations of CIP solution.
46. Log for changing air filters is best ever seen because they check every air filter every day.
47. Note: PP #6 talks about reconciliation of vitamin usage daily by weight. Most current reconciliation results in 108% and 112% which is excellent.
48. Prerequisites are silent on facility or premise. In prerequisite #3 & 5 were silent on piping cross connections. Also silent on piping cross connections for cleaning solutions.
49. Prerequisite on cross contamination is silent on raw to pasteurized contamination except through regenerator of the pasteurizer.
50. The storage of single service containers - needs to be stored in a clean dry area as

per the PP but actually stored in CIP room that does have water and is not dry room.

51. The prerequisite on water safety required boiler water additives to meet 21 CFR 310 but the only documentation provided to address the PP requirement was USDA accepted, not according to 21 CFR. Approval letter should reference 21CFR instead of USDA compliance

52. Stainless 10 gallon cans found in processing room with milk residue in them. Training is that employees are to hand wash cans or replace with clean one but appears this is not being done. Also not in any prerequisite and no hazard analysis

53. Heat treated cream silo chart uses chart with temperatures progressing from high to low toward the center of the chart. This makes it difficult to determine time.

54. The heat treated cream load-out is done with the tanker manhole lid partially raised with no overhead protection or filtering.

55. The designation of the corrections for a PP is titled a “Deviation Log” when in reality it is a “Nonconformity Log”.

56. Eliminate use of nonspecific terms in the PP such as “should”.

57. Construction of the powder horn is formed into table top and there is potential for drainage off table top into powder horn.

58. Storage of toxic compounds is a problem because stored in areas adjacent to packaging materials. Toxic chemicals found outside of toxic storage area.

59. Very good system for cleaning transports prior to begin loading; however, we recommend that the cooler be protected from the aerosolized over-blow and debris.

60. Housekeeping on premise, outside has inadequate drainage. Also a problem throughout facility with maintenance. Need adequate drainage of outside drains

61. PP program appears to be in very good shape. Very good content including identification of records, frequency of records, corrections, examples of records.

62. Flies appear everywhere including inside the processing area. Maybe partly the result of negative air pressure in the processing room.

63. 10 gallon dump cans all over and very common. Question of whether temperature of product is maintained until stored in the cooler.

64. PP 3 contains info. on maintaining diff. pressure as needed but does not address integrity of seals for diff. pressure controller.

65. PP #5 Protection from Adulteration is where all allergens are addressed. Good job on allergens, but for some reason the diff. pressure info repeated from PP#3.

66. PP#7 Employee Health conditions, does not cover high-risk activities. Employee handbook only talks about lesions on hands, and employees as to wear gloves but does not address food borne contagious illnesses.

67. PP#8 Exclusion of Pests does a good job on chemicals, traps and bait stations but

should have references on construction to preclude entrance of pests. Reference problem is with flies.

68. The brief written description of each prerequisite should contain the description, numerical values or other details that define control (i.e. ozone level and UV light intensity for plant water prerequisite). This information can then be used by the plant and regulatory agency to determine control and compliance.

69. Corrections to operational problems in the Prerequisite Program are generally effective and timely, but tracking and documentation of repeat occurrences in a central record is not available. Comment: This may have an impact on the adequacy of the oversight by the regulatory agency also.

70. Supplier control prerequisite may be needed to better document safety, storage, inventory control and allergen issues.

71. Pest control done by outside contractor. The Pest Control plan was comprehensive and adequate, but there were no records available to verify that procedures in the plan had been performed.

72. COP records monitor cleaner/sanitizer strength and temperature but did not indicated what parts were cleaned and were not initialed by the operators. (Note: not carried forward by Evaluation Team since not required by pilot or plant's written HACCP program.)

73. The HACCP Committee needs to assign a group or individual to put together a model prerequisite guide that covers at a minimum the eight mandatory prerequisites and includes a model form or checklist to specify the minimum amount of information to be included by the plant in the “brief written description”.

74. More extensive consideration of allergens for all products would strengthen HACCP program.

75. Manual records system for raw silo temperatures that log temperatures every 15 minutes not frequent enough to identify potential temperature problems and computerized temperature recording system is in advanced stages of failure. This needs attention through increased manual logging frequency or replacement of the computer system.

76. Appendix N testing records for incoming condensed milk should use the same system as established for incoming raw milk tankers to reduce confusion.

77. Prerequisite on pest control was not being effectively documented.

78. The prerequisite for equipment design stating all new equipment will be reviewed and inspected by the State Regulatory Agency is not consistent with the plant’s intent to have only significant, complex, unique or large pieces of equipment reviewed and inspected by the state prior to being made operational.

79. High piping between booster pump and raw regenerator in HTST #4 prevents natural drainback during unexpected shutdowns of system.

80. Contamination with pathogens is also apparently considered to be a potential hazard.

81. Cleaning PP is listed. The Transportation and Storage PP indicates tank cleaning frequency but procedures are outlined under Food Contact Surfaces. Again, internal consistency throughout the HACCP System is important. When dealing with a PP there should be documentation, a brief written description or checklist, that outlines procedures for implementation, monitoring and correction. This serves as a basis for auditing.

82. Storage and Pest Control PPs are not consistently named with the actual PPs. Storage and Pest Control PPs probably are contained in portions of the 8 mandatory PPs and are to be in place even in the absence of the requirements of the HA.

83. The titles for Cleaning PP and Adulteration PP do not match up with program titles. There should be internal consistency which allows the plant to audit the plan routinely. Without this internal consistency from HA through descriptions of the programs, monitoring, corrections and documentation, the PP cannot be audited.

84. PP for air blows are used throughout plant to move past. product. Not considered in HA.

85. PP for equipment sanitary design requires 3-A or equivalent construction. CC drainer has woven material belt, rough welds and exposed bolts in product contact area. This is why one of CC line has metal detector.

86. If plastic lidded containers that go through cheese drainer need to be screened with metal detector to prevent hazard, why do foil lined containers not need same screening?

87. Records for ozone level and UV light intensity or functionality need to be maintained for the plant process water.

88. Problem with corrective follow-up on problems identified in monthly internal audits (30 repeated problems).

89. Monthly internal audit forms identify problems but same problems are noted month after month.

Hazard Analysis

Recommendations

1. Modify the pilot document prior to incorporating it into Appendix K:
    - To include a statement under the implementation section to encourage the use of the preliminary steps in the development of the HACCP plan. (see Appendix K)
    - To require up-to-date flow diagrams as part of the contents of the HACCP plan. (see Appendix K)
2. See the Hazards and Controls Guide, guidance on how to assess a microbial hazard on the basis of microbial characteristics and existing plant conditions, i.e. vegetative or spore-forming, growth requirements, pasteurized product, toxin production, etc. (Use extracts and the chart from the Bad Bug Book and Seafood Training Manual.)
3. Include in the Hazards and Controls Guide, guidance on the hazards associated with common plant chemical compounds, adulterants, vitamins and components that can cause allergens and sensitivities.
4. By acceptance of this report, the NCIMS HACCP Committee directs the Training Subcommittee to modify the hazard analysis summary form so it is more user friendly and intuitive.

Findings

HACCP is based on the determinations made in the HA. It must be complete and identify all Potential hazards. Following are the major observations.

1. Completeness of the hazard analysis was often an issue. The individual steps of the hazard analysis is dependent on a complete and accurate flow diagram listing all steps, processes and inputs as well as a complete list of ingredients. The current document does not require a written flow diagram.
2. Common steps between products were sometimes inconsistent between flow charts.
3. Hazard analysis is dependent on the availability of technical expertise with good technical information. Most plants requested some assistance in identifying and assessing hazards.
4. The hazard analysis form most often used is the one that was presented in training. It was inconsistently filled out in column 3 for the determination of reasonable likelihood of occurrence.
5. Listeria in finished products was often not identified as a potential hazard on the hazard analysis form. This organism probably is associated with the most food safety concerns of any in pasteurized product.
6. Plants often were inconsistent in how they dealt with an identified potential hazard such as allergens, vitamin intoxication, and therapeutic drug residues.

Observations: Note - These observations are very site and date specific, representing individual team member's observations. Individual observations were captured for further discussion and later evaluation by the complete Evaluation Team. Many of the observations are based on requirements listed in the plant's HACCP written program and are not requirements of the NCIMS HACCP pilot program.

1. Product returned in company owned distribution trucks from stores that stayed on truck is reworked, if it meets certain criteria in the PP. This needs a hazard analysis
2. Flow diagrams are equipment specific, not product specific
3. There needs to be additional research to obtain true scientific information regarding the potential generation of Staph. aureus toxin production and development to support or modify the current four hour rule of thumb. This issue is being faced by almost all pilot plants in their product hazard analysis.
4. The hazard analysis for many products includes a hazard for animal drug residues in the raw milk receiving step. A "yes" in column 3 (potential food safety hazard is significant) means that its likely to occur even in light of properly applied PPs and will require control by a CCP. This concept in the use of the hazard analysis form used by the HACCP Committee in its Baltimore training does not appear to be understood by the HACCP plants. The NCIMS HACCP Committee needs to either provide better guidance on the use of the hazard analysis form or scrap the form and use the IDFA form or another one that is more intuitive to the plants filling them out.
5. Cottage cheese vats not protected during set and open to airborne contamination, such as from aerosols created by water hoses. Room opens directly into processing room and traffic from processing and packaging areas can contribute to contamination. Hazard analysis should address airborne contamination as potential hazard
6. The hazard analysis for a number of products lists vitamin intoxication as a hazard, managed by Operating SOPs. A review of the operating SOPs does find statements indicating control. It would be better to address this potential hazard in a prerequisite program.
7. The records documenting the ongoing application of the PP's are adequate and complete. The NCIMS HACCP Committee needs to provide additional guidance in the HACCP document on standardizing and formalizing procedures for checking the prerequisite performance
8. The hazard analysis for eggnog lists microbiological contamination as potential for caps and cartons as "Not likely to occur" but justification does not list purchase from an IMS listed source, yet this is a requirement of their HACCP pilot program
9. Common portions of flow charts should be standardized to reduce duplication and minimize the possibility of discrepancies when changes are made. Common sections of flow charts could be represented by one flow chart to simplify things. The current duplications requires one change to be reflected in many flow charts and hazard analysis, increasing the possibility of forgetting to update one of the affected flow charts.
10. The hazard analysis identifies biological hazards for pathogens at the raw receiving

step. The monitoring temperature is described as being for the storage area, but it should be for milk in tankers.

11. The hazard analysis does not flow to the prerequisites and monitoring. The prerequisites are often very generally stated so it is difficult to determine what is monitored, by who, and what is acceptable.
12. The hazard analysis did not include rework.
13. Rework is not included on any flow diagrams for products. Potential hazards are not identified or evaluated and also because of storage of rework and possible temperature abuse.
14. The pests and rodents are noted as a hazard in the hazard analysis with the Transportation and Storage prerequisite listed as the control for most products at the "Receiving" step. The prerequisite that does address pest and rodent management is the Sanitation and Pest Control prerequisite.
15. Internal audit procedures-- not using plant-initiated internal audits. The plant using the results of their third party audits
16. In the hazard analysis for a number of the products with the raw milk receiving step, drug residues are listed as a significant hazard by indicating a “Yes”. This conclusion requires control through a CCP at this step or a future step, yet the justification is listed as Appendix N. Use of form not straight forward and NCIMS HACCP committee needs to address use of this form, additional instruction and training or scrap form for another form.
17. The first three columns for the hazard analysis are used appropriately but the rest of the columns appear to be misunderstood and need to be addressed by the HACCP Committee since this has been a consistent problem by most plants, i.e. receiving step with biological pathogens. The 4th column on justification states “A subsequent step will eliminate pathogens.” This is not adequate justification. 5th column on control measure does not need to be filled out if column #3 is “No”, but most of the time column #5 is filled out.
18. Foreign material is listed as a hazard in a number of product “Receiving” steps and controlled by the Transportation and Storage and Equipment prerequisites. A review of these programs shows that foreign material is not directly addressed in either. It is more common for foreign material to be controlled through the use of strategically located filters and screens which are not listed in any flow diagrams or product hazard analysis.
19. Sanitizer residues listed as a hazard in the raw milk storage step under the hazard analysis for a number of products notes that it is controlled by the Sanitation and Pest control program and is addressed there in general terms, i.e. #9 on page 2. However records documenting this to prove sanitizer or cleaning solutions are not left in storage tanks during filling with product do not exist. There is a procedure for inspecting a tank prior to filling but this is not referenced in the Sanitation and Pest Control prerequisite.
20. Allergenic contamination with eggnog base is not listed as a chemical hazard for any

products. The Allergen prerequisite describes in general terms the management of allergic ingredients but does not address frequency of cleaning, separation of lots or batches or sequence of processing to manage these items.

21. Ammonia contamination is listed as a hazard for a number of product hazard analyses under the raw milk storage step but not specifically mentioned in the Equipment prerequisite program. Found in two different places. This is not generally a hazard in food products, but a quality issue.
22. For a number of product hazard analyses, “contamination from raw milk side of unit” for the HTST is listed as a hazard with control occurring through the Equipment prerequisite. This is a cross contamination issue; however, it is not addressed in the Equipment prerequisite other than general references to calibration of equipment.
23. The flow diagrams were not complete and did not include Salvage Milk.
24. The cooling step for heat-treated cream (this step was shown on the white milk flow diagram but not on the cream flow diagram).
25. Water and air are not included for any product.
26. The hazard analysis for large curd products under the step for storage, identifies sanitizer residue as a hazard in the Transportation and Storage and Personnel PP but these do not address the issue. Should indicate the Sanitation and Pest control PP.
27. Vitamins are not addressed as a potential hazard for any products run on HTST #1.
28. The control of the hazard for introduction of pathogens at the blending step of a number of products indicates post pasteurization contamination and control is through the Personnel prerequisite. This prerequisite does not adequately address measures to be used to control post-pasteurization contamination. This hazard is more likely controlled through GMPs, employee training and the Sanitation prerequisites.
29. No hazards identified except biological hazards and chemical antibiotics. No physical hazards such as metal noted.
30. No guidance on sensitive ingredients in pilot document. Should be included in pilot document, in training and in hazard guide.
31. Recommendations might be made that the flow diagrams include conditions such as time, temp and pH, if useful.
32. Hazard analysis of different products noted where hazards were controlled, but no hazards were identified. No evidence of consideration of certain ingredients and packaging.
33. PP7 Employee health conditions-- high risk conditions were not addressed, diseases not addressed.
34. Flow chart lacked several steps, fruit receiving, raw milk pasteurization and separation, cream, blend, culture media blending and rehydration, leading it to be

incomplete and misleading. Because of this, these steps were not considered in the hazard analysis.

35. Other flow diagrams were mostly complete, but missing some steps (packaging).
36. Hazard analysis for triblender did not consider that it was used for raw and pasteurized product on the same day.
37. Ingredients were held to be proprietary, no letter of guarantee for cert. of analysis. Need an FD&C letter of guaranteed compliance.
38. Letters of guarantee were present.
39. Sensitive ingredients and allergens not evaluated on the hazard analysis.
40. Hazard analysis did not show complete consideration of hazards on the summary table.
41. The following steps including raw receiving- physical, silos - chemical, cream storage - biological and chemical, and rework list no potential biological hazards.
42. Hazard analysis column 3 heading used the heading “does this hazard need to be documented in the HACCP Plan?”
43. Eggnog flow chart is very thorough.
44. Evaluation Team liked the way the role of the PP was identified in HA worksheet but would like to see a little more on individual procedures.
45. The written HACCP plan does not include all processing steps (washer cooler for fruit on the bottom yogurt), ingredients (concentrated milk for eggnog), and potential hazards (i.e. juice into milk, listeria in pasteurized product, curd washing for cottage cheese, HTST cross-connections). In addition, the some sub-processes should have their own flow chart, i.e. concentrated milk and raw milk.
46. Usually the HA does not list PPs for justification when no hazard has been identified. In this case, they were. However, allergens and sensitive ingredients as well as vitamins should be considered at this step. The same is true of the next step on non-dairy storage.
47. Drug residues are identified as the hazard but the control step is a β-lactam test. Drug residues should refer to specific drug residues, i.e. β-lactam test. Hazards need to be specifically addressed. Drug residues as a hazard without being specific and if this nets out a CCP, then what are the critical limits. Do you set critical limits for all possible drug residues?
48. Staph. toxins are identified as a potential hazard, but when evaluated, they are determined to be not likely to occur. The justification indicates time and temperature for tankers. This becomes a required prerequisite program and must have evidence and records of implementation, monitoring, corrections. What is the scientific basis that the occurrence is unlikely? The Receiving Operation Checklist does not necessarily indicate parameters and show that a procedure is in this place to make this decision.
49. The Receiving PP is supplementary justification and should appear as a justification

rather than a control measure. Prerequisite programs which justify the determination that a potential hazard is not likely to occur should be clearly identified in the hazard analysis. This should point to the implemented procedures and their documentation.

50. The Grade A storage step on the HA Worksheet again lists pathogens as a potential hazard. In this case the hazard seems to be presence and growth of vegetative pathogens, including production of staph toxin. Growth is inhibited by time and temperature control in the PP entitled Transportation and Storage. The HA erroneously indicates a PP which is Time and Temperature Storage. The PP should indicate a documentation of these procedures.

51. The raw milk receiving step as well as step 1 in the HA indicates heat-treating will destroy pathogens. We probably should use the term pasteurization to be clear and consistent in our terminology. Several observations noted above for condensed also apply to this step. Physical hazards were not identified, but the justification indicates they will be filtered out by tankers. In addition the next step is a filter. The assumption is this is a quality step and does not indicate the presence of a hazard.

52. The raw milk storage step results in many of the same observations as HA step 2. In this step and in step 2, calibration is listed as a PM control measure. In HACCP, by definition, calibration is considered to be a validation step under the verification program.

53. Blending identifies no potential hazards, but justification mentions several PPs including cross-contamination, which addresses allergens. The PP preventing cross-contamination addresses egg nog as a potential allergen. It does not address the potential for milk to contaminate juices run on Grade A equipment. The plant operates under a HACCP plan for juice (outside of NCIMS responsibility).

54. It seems unusual, because within the last 20 years, major outbreaks have occurred from the contamination and growth of Listeria in refrigerated, pasteurized milk. These have resulted in deaths. Therefore, pasteurized milk products should probably have Listeria identified as a potential pathogen. If the likelihood of occurrence is low due to the presence of properly implemented prerequisite programs, then identify the programs and their documentation, but don't ignore an obvious potential hazard.

55. Non-dairy ingredients and packaging, especially compounded ingredients, labels and packaging need to be considered individually to focus on specific hazards such as allergens and sensitive ingredients.

56. Fruit on Bottom HA - Washer Cooler is listed process step but not considered in HA.

57. HTST Past. does not reference PP on cross connections. PP on cross connections is not complete enough to have provided meaningful guidance regarding problems found on past. #4.

HACCP Plan

Recommendations

1. Include revised pasteurization models in Appendix H of the PMO. (see PMO revisions)
2. Add wording in section 7 of the PMO which requires compliance with all the items of 16p and the requirement to manage pasteurization as a CCP. (see PMO revisions)

Findings

The HACCP plan itself usually listed only the control of vegetative pathogens at pasteurization. In most cases other identified potential hazards were justified as not likely to occur in light of prerequisite programs.

1. Pasteurization models were found to be helpful. They need to be updated to include HTST, HTST with magnetic flow meters, and vat pasteurization.
2. There was some inconsistency in applying the pasteurization model that was furnished during training.

Observations: Note - These observations are very site and date specific, representing individual team member's observations. Individual observations were captured for further discussion and later evaluation by the complete Evaluation Team. Many of the observations are based on requirements listed in the plant's HACCP written program and are not requirements of the NCIMS HACCP pilot program.

1. Document entitled "CCP Summary Table" under the section entitled recordkeeping only refers to temperature charts reviewed by supervisor but not flow rate records. Both HTSTs have mag. Flow meters.
2. The overall HACCP plan was very good, but implementation appeared to be a hybrid between unmodified prior or existing programs and the needed HACCP plan items.
3. One operator's documentation of pasteurization charts was incomplete over a three year period without correction. This was a very long period of time for lack of correction of such an important record
4. HACCP Summary Table does not address the pasteurizer seal integrity.
5. Quarterly calibration of pasteurizer done by state regulatory.
6. PP# 3 Prevention of Cross Contamination uses cut in and cut out as a separation of raw and pasteurized. Does not include the differential pressure, doesn't mention proper interwiring.
7. No PP for adequate holding time in past. Should this be incorporated in the model?
8. Critical limits are intended to reflect scientifically based maximum or minimum values to represent control of the CCP. The plant has used operational times and temperatures for its critical limits. Recommend modifying identified pasteurization times and temperature critical limits to reflect minimum acceptable pasteurization

times and temperatures. A CCP is identified as 175 degrees F. This critical limit should not be identified on HA but on CCP Summary Table also called HACCP Plan form. When noted, we should call this critical limit “pasteurization above 175 degrees F” to distinguish it from a simple heating step.

9. The plant has chosen to lump eggnog and 2% low fat together on the same flow chart. The following ingredients were not broken out: Sugar, Eggnog Base, Guar Gum, Carrageenan, Packaging - gallon jugs, caps, and labels. By grouping non-dairy ingredients together, the egg yolks, an allergen in the eggnog base may not be accounted for on the hazard analysis. Packaging, together with the labels, need to identify egg yolk as a potential allergen, may be overlooked. All components of eggnog should be entered on the flow chart as ingredients. The individual ingredients would therefore have their own flow chart and hazard analysis.
10. Pathogens should be more clearly identified, such as vegetative or spore-forming. Clearly both may be present in the food. More clearly indicating which vegetative pathogens are expected, gives the opportunity to assess the likelihood of occurrence and properly design and choose control measures. In this particular situation, most vegetative pathogens are destroyed by the control measure of pasteurization, but the type of occurrence, such as presence, contamination contributed at this step, growth, destruction, or toxin production cannot be assessed by simplistic annotation.
11. Computer Controls: HACCP program is silent on computer controls for past. except for general statement requiring PMO compliance. HTST #4 computer controls adequate, operational computers appear appropriately isolated from Public health safe guards, however HACCP system should be used to monitor and verify continuation for these controls.
12. The HACCP Committee should consider modifying its pasteurization model to place all traditional pasteurization public health control measures in a unified model.

Corrective Actions

Recommendations - None

Findings

Corrective actions to the violation of critical limits were generally in order. This was probably due to the fact that there are considerable automatic controls to pasteurization and these were familiar to both the plant and the regulatory agency through long implementation. Plants rarely included CCPs in their plan other than pasteurization.

Observations – None

Verification and Validation

Recommendations

1. Modify the pilot document prior to its incorporation into Appendix K, under Prerequisite Programs "2. Monitoring and Correction" to require that devices such as thermometers used to monitor PP's be calibrated. (see Appendix K)
2. The Evaluation Team recommends that there is a need to establish a permanent method to provide expert technical guidance regarding the NCIMS HACCP Program to both milk plant HACCP Teams and State/FDA Auditors. Our recommendation includes extending and making permanent the NCIMS HACCP Technical Resource Team composed of state, industry and FDA personnel (place in the NCIMS proposal).
3. Upon acceptance by the NCIMS HACCP Committee, the Training Subcommittee shall provide additional training on verification/validation to increase its understanding and priority, especially reassessment.

Findings

In the HACCP pilot, the verification program shall evaluate whether the HACCP system is being implemented according to design. In addition, there are requirements to validate that the HACCP plan is adequate to control hazards that are reasonably likely to occur.

1. Calibration of process monitoring instruments under the verification program sometimes did not extend to those instruments used in the HACCP system other than the pasteurization equipment tests and thermometers.
2. Sometimes, in a few plants, basic calibration information such as comparison of indicating and recording thermometers and checking of cut-in and cut-out were not always entered on the records
3. The volume of records generated in some plants resulted in the review of records that was very time consuming for plant personnel and difficult to complete, i.e. monitoring of critical control points, taking of corrective action, calibration of process monitoring instruments, etc.
4. The Phase II pilot document was not clear resulting in some confusion about the need to verify regulatory seal integrity and the frequency.

Validation of the HACCP plan and the hazard analysis shall occur at least once in 12 months after implementation and at least annually thereafter.

1. Annual verification and required reassessments were not observed being accomplished in several plants.
2. The validation is to be performed by a "qualified" individual who has been trained. There is a question whether just having the Dairy HACCP Core Curriculum training produces a qualified individual capable of conducting a hazard analysis and determining controls in the absence of technical training and experience without specific guidance.

3. Records of validation of the hazard analysis after product and process changes were not common in plants.
4. Plants were often not in a position to validate that an identified potential hazard was not likely to occur to the satisfaction of the regulatory agency. This caused conflicts with the regulatory agency when the regulatory auditor did not accept the findings of the hazard analysis. An example of this was the potential hazard of staph. toxin production in the cream pot. This is one example of the need for the Technical Resource Team.

Observations Note - These observations are very site and date specific, representing individual team member's observations. Individual observations were captured for further discussion and later evaluation by the complete Evaluation Team. Many of the observations are based on requirements listed in the plant's HACCP written program and are not requirements of the NCIMS HACCP pilot program.

1. In HACCP Plan under CCP planning, the document states equipment tests are done by the state. This is not in compliance with the NCIMS HACCP pilot document.
2. The calibration of pasteurization equipment referenced that the state regulatory agency is responsible for accuracy and timeliness of equipment tests.
3. Pasteurizer flow charts are not verified by individual that has been appropriately trained. The operator on HTST #2 recorded a cutout as 165.8ºF. This would indicate that the state seal registering a cutout of 166 ºF was no longer valid, which is not likely. Note: It appears that the operator was doing this test too rapidly and incorrectly reading the temperature from the recorder instead of the indicating thermometer.
4. Charts overlap repeatedly and noted by verifier but not corrected.
5. HACCP plan needs to be revalidated since it has been slightly over 1 year since last validation.
6. CIP charts are not dated by the verifier as per NCIMS HACCP document.
7. Audit for 8a included in HACCP plan records. Specific item requires event pen to indicate forward flow based on flow rate but charts did not show clear movement between forward and divert events. May take up to 7 minutes to complete movement.
8. CIP charts: Some the pens on the recorder were not working for several days in a row. Stamped as being verified but did not correct pen problem until a day after being verified.
9. Some of CIP charts overlap. Was not noted by operator or verifier. One of the pasteurizers was wired with the cleaning computer so part of the public health controls could be overridden, preventing the separator from valving out and overriding the public health controls. Also, valving out for the separator requires the control of three valves, one of which has the spring operating in the wrong direction.
10. The plant did not address the role of regulatory seals in its HACCP program.

11. The “verification” column for the CCP or HACCP Plan Summary table is not complete, i.e.:
12. Nothing addressing the comparison of the indicating and recording thermometers when changing charts.
13. Integrity of the seals not addressed.
14. The pasteurization equipment controls tests conducted on HTST #2 by the state regulatory auditor did not adequately address all public health requirements. Specifically: The cream separator that was an integral part of the system did not “valve out” as required.
15. The use of a master-cleaning schedule pulled many disparate things together but was a little hard to follow because of the varying frequency for all the various individual activities.
16. To improve flow of information between records we suggest the verifier or monitor be trained to mark through those places on forms that are superfluous so there are no blank spaces. Examples of this are checks only done weekly when there is a space for every day, or in those cases when the facility may be down and not processing.
17. The product flow diagrams should be verified annually and each time there is a change which might affect the hazard analysis in order to make sure they are complete and include inputs such as water, air under pressure, and rework or salvage. These flow diagrams are key to the conduct of the hazard analysis. Process steps or ingredients not accounted for on the flow diagram will probably not be considered in the hazard analysis. Consequently, they may be left off the HACCP plan or out of the mandatory prerequisite programs. It had been a little over a year since the last verification
18. It appears there was uncertainty by the plant verifiers about the correctness of information on the HTST recorder-controller charts and magnetic flow meter charts.
19. The NCIMS HACCP committee needs to modify the training on verification to include specific direction for the verifier on the HTST charts and what items to verify.
20. No requirement in the document for calibration of non CCP monitoring devices.
21. The centralized approach to maintaining the HACCP written program, oversight and verification creates a huge burden on one individual resulting in some deficiencies caused by lack of time and failure to delegate.

Records

Recommendations

1. Modify the pilot document prior to incorporation into Appendix K, to require as part of the industry's HACCP written program:
    - Table of Contents
    - Document Change Log
    - Plan validation dates
2. Modify the pilot document prior to incorporation into Appendix K, under "Records" item #1, "Required Records" to reflect need for consistent terminology, a centralized list of records, and dates or version numbers on all documents. (see Appendix K)

Findings

The HACCP pilot generated numerous records. In some cases, HACCP was integrated with corporate quality control systems or with ISO 9000 or other management systems adding to the deluge of documents.

1. Document control is a big issue in HACCP plants. Some documents were inadequately identified causing the paper trail to be confusing.
2. A master list of monitoring records found in a couple of plants was extremely helpful.
3. Some plants included copies of blank monitoring forms with the HACCP plan. This was also found to be helpful.
4. Documents referred to in the hazard analysis had been changed or their use had been discontinued.
5. Sometimes the current revision of documents was not clear due to failure to date the form and properly identify the revision.
6. Pasteurization records sometimes did not contain information required by the PMO. The Phase II pilot document was not completely clear regarding this.
7. In some plant, the large numbers of automatic records produced as in the case of mechanical cleaning records made them difficult to verify. Some plants were not taking advantage of the ability of their systems to produce automated mechanical cleaning exception reports to alleviate this deluge of records that needed to be checked.

Observations Note - These observations are very site and date specific, representing individual team member's observations. Individual observations were captured for further discussion and later evaluation by the complete Evaluation Team. Many of the observations are based on requirements listed in the plant's HACCP written program and are not requirements of the NCIMS HACCP pilot program.

1. Each page of the written PPs, hazard analysis, HACCP plan and other pages of the HACCP program should be dated, with a new date added whenever the page is updated.

2. Prerequisites are decentralized and not readily available in one area
3. Include a summary page at the beginning of the HACCP program that dates and briefly describes each change to the written HACCP program.
4. There is a strong need for a standard format for records produced in the plant. Most formats for records in this plant are similar and relatively easy to follow. A suggestion would be that each record have an identifying name and a place for comments and verifier's remarks and signature.
5. HACCP certification has directly and positively affected the plants ability to acquire new business.
6. Pilot document-- master list of monitoring records would be especially helpful.
7. Pasteurizer charts do not record low flow alarms or loss of signal or high flow rate alarms.
8. The cleaning charts show cleaning circuits being repeatedly not identified (5 of same circuit charts had one or more missed circuits in last 20 days). Need to be addressed by HACCP team and production personnel to achieve permanent correction. Five unidentified cleaning circuits in last 25 days on CIP charts.
9. A centralized deviation log was complete and accurate but could have been better organized.
10. Silo temperature monitoring instruments were malfunctioning and had done so for an extended period of time. Log being used to monitor temperatures was not adequate.
11. A ledger should be established to record the details of all pasteurized equipment checks on one page. State and plant should maintain ledgers for each pasteurizer in order to accurately and easily determine whether all required tests are being done at required frequency.
12. The HACCP Committee should provide more written guidance on what is expected on HTST pasteurization charts and computer controls related to public health controls (use PMO as guidance).
13. Cut in and cut out not being conducted properly
14. Charts have improved substantially since last visit
15. Last four state equipment tests required adjusting the recording thermometer. No adjustments noted on the chart by operators
16. Regulatory tests show the cutout between 167.5ºF and 167.8ºF but charts do not reflect that. Charts show at 167ºF. Temperature changes too fast to discern.
17. For one of the pasteurization equipment control tests conducted by the state regulatory auditor, the cut out temperature was recorded as 164° F but the legal “cutout” temperature should have been at least 166° F. There were no indication that the regulatory auditor recognized this was below acceptable pasteurization temperatures. The cut out temperature on the daily operational recorder charts was listed as 166° F before and after the incident. The cut out temperatures on the pasteurization equipment tests conducted by the state, prior to and after the incident,

were recorded as 166° F.

18. A document control program should be put in place to identify PPs and procedures as well as their related documents and records. This should include all HACCP plan documentation. The Table of Contents for the various PPs has numerous mistakes, as mentioned before, titles are inconsistent.
19. Recommend summary of records for PP and CCP monitoring and verification records be included in the HACCP program. The Evaluation Team had some difficulty locating all HACCP program documents. The NCIMS HACCP Committee needs to be more specific in the pilot document and training regarding the listing of documents used to monitor prerequisite programs and CCPs. Some ideas include a summary records table or examples of blank documents to facilitate verification and auditing. Also, the storage of these records should be organized and identified.
20. The HACCP Committee should add language or recommendations to improve the effectiveness of the employee HACCP training program so when a form is provided for employee monitoring, a short description of the procedure to be carried out should be documented and training of the employee should be documented. This training should be based on the procedure for carrying out the program, how to fill out the form, correcting entry errors, when comments are required on the form, and who to notify or which corrective actions are to be taken when there is a departure from the procedure.

Regulatory Sample Testing

Recommendations - None recommended in this category

Findings

Regulatory samples were being tested in accordance with the current PMO and associated documents.

Observations Note - These observations are very site and date specific, representing individual team member's observations. Individual observations were captured for further discussion and later evaluation by the complete Evaluation Team. Many of the observations are based on requirements listed in the plant's HACCP written program and are not requirements of the NCIMS HACCP pilot program.

1. State regulatory sampling was complete and timely, except for fruit on the bottom yogurt which was produced for 3 months before the first samples were taken.
2. HA lists drug testing for condensed milk as CCP. Charm SL test being used for this and had not been evaluated and accepted by FDA for this product.
3. Regulatory samples met minimum frequencies for products and water with a few shortcomings listed below.
   a) Warning letters not sent as necessary.
   b) Condensed milk only 3 samples from 2/2000 to 4/2001.
   c) Eggnog twice sampled in Dec. 2000.
   d) No samples for fruit on the bottom cottage cheese.

Pasteurization and Aseptic Processing Equipment Testing and Sealing

Recommendations

1. The Evaluation Team recommends that the document clarify that the industry is also responsible for the performance of all required Pasteurization and Aseptic Processing Equipment Tests (see PMO revisions other than Appendix K).
2. Prior to incorporating the pilot document, make changes to 16p(E)2 to require that the state regulatory agency physically supervise pasteurization equipment testing every six months. Regulatory supervised tests shall include the semi-annual HTST and HHST pasteurization tests.(see PMO revisions other than Appendix K)
3. Prior to incorporating the pilot document into Appendix K, make changes to "Verification" to indicate that critical factors for aseptically processed products be managed separately from the HACCP system as required by 21 CFR 113, even if identified as a CCP in the hazard analysis (see Appendix K).

Findings

Protocols for who conducted the testing and sealing of pasteurization systems varied from state to state. It was the intention of the pilot program to allow the plants to be responsible for routine testing and sealing of the pasteurization system, with the regulatory agency present to verify that the tests were being properly conducted at least semiannually.

1. Some states were reluctant to allow the plants to conduct testing and sealing on their own.
2. A few plants wished to rely on the regulatory agency to conduct testing and sealing.
3. In states where testing and sealing was conducted by qualified plant personnel, there seemed to be no more issues with plant personnel conducting pasteurization checks than with the regulatory person performing these procedures.
4. Criteria for testing vat pasteurizing equipment needs to be delineated. There is a question as to whether state regulators must physically supervise vat pasteurization recorder tests semiannually.
5. There was confusion about how to deal with aseptic processing critical factors. Should they be a CCP?

Observations Note - These observations are very site and date specific, representing individual team member's observations. Individual observations were captured for further discussion and later evaluation by the complete Evaluation Team. Many of the observations are based on requirements listed in the plant's HACCP written program and are not requirements of the NCIMS HACCP pilot program.

1. How to deal with regulatory agencies and 6 month test for aseptic and vat pasteurizers.

2. Process records were complete, accurate and properly documented. This is substantially improved from the last time.
3. Timing pump was not sealed.
4. Product balance tank was uncovered. Note: if the lid had been in place and the return line properly connected, there would have been a cross connection with raw product.
5. Water balance tank chemical line was left connected during processing. If disconnected, this swing line is blocked by pipes and cannot be swung free from the tank
6. The NCIMS HACCP Committee needs to resolve a difference of interpretation regarding the authority and responsibility of pasteurized equipment checks by the state regulatory agency and the plant.
7. Pasteurizer and processing charts do not record low flow alarms or loss of signal or high flow rate alarms
8. How to address critical factors under a low acid canned food program in HACCP.

Training and Standardization

Recommendations

1. Upon acceptance by the NCIMS HACCP Committee, the Training Subcommittee shall coordinate with the Standardization Subcommittee to better understand decision points related to state regulatory and rating responsibilities such as listing related to FDA, state auditors and listing officers.
2. Upon acceptance by the NCIMS HACCP Committee, the Training Subcommittee and Standardization Committee shall delineate clear procedures for use of the Audit Report Form and address any training needs in this regard.
3. Modify the pilot document prior to its incorporation into Appendix K to note that persons who have been trained in accordance with the Dairy HACCP Core Curriculum must verify CCP monitoring records. Note that personnel who review PP records do not have the requirement to be trained under the Dairy HACCP Core Curriculum. (see Appendix K)
4. Upon acceptance by the NCIMS HACCP Committee, the Training Subcommittee shall emphasize the importance of pasteurization training courses by coordinating with the State Training Branch to increase the frequency of offerings that emphasize the installation, operation, testing, and verification of the pasteurization system.
5. Training Subcommittee shall revise the Orientation portion of the Dairy HACCP Core Curriculum to incorporate recommendations and changes and coordinate with the State Training Branch to produce training, which can be accessed remotely by both regulatory personnel and industry.

Findings

Prior to the Evaluation Team's work, training seemed to be adequate for the pilot, but the Evaluation Team found that there are gaps in the training of plant and regulatory personnel across both HACCP and the traditional system.

1. Some regulatory personnel, especially state auditors and listing officers, expressed a lack of confidence in fully understanding their roles and responsibilities, particularly with regard to regulatory and listing decision points.
2. Some regulators expressed a lack of understanding in how to properly fill out the audit report form.
3. Opportunities to address the findings mentioned in other categories in training courses abound.
4. While industry seems to have adequate resources for training, some state regulatory agencies could not spare the personnel time to send people to training even when the FDA was paying the travel and expenses.
5. Verifiers were often overwhelmed because of the requirement that only those who have been trained under the Dairy Foods HACCP Core Curriculum may perform required records reviews.
6. Prerequisite program records verification under the HACCP system is time consuming and may not be appropriate to the importance to the record being reviewed. Other plant personnel might be able to accomplish the task as well as the HACCP-trained individual, especially for those PP's that are not used to reduce the likelihood of occurrence of a potential hazard.
7. Those plants that had an on-going and periodic training program with comprehensively documented programs had more robust and better functioning HACCP programs.
8. The team noted some cases where the training of the regulator and the plant personnel seemed to be inadequate in pasteurizing system installation, operation, controls and testing.
9. National training with the pilot plants and participating state agencies receiving the same training under the Dairy HACCP Core Curriculum has been helpful. Since industry has available to them other training, and the FDA is planning to use standardized training on the HACCP principles, minimum requirements for this training and specialized training under the core curriculum will need to be considered.

Observations Note - These observations are very site and date specific, representing individual team member's observations. Individual observations were captured for further discussion and later evaluation by the complete Evaluation Team. Many of the observations are based on requirements listed in the plant's HACCP written program and are not requirements of the NCIMS HACCP pilot program.

1. The plant had not established a documented system for training of individuals with monitoring responsibilities for CCP(s); however, annual HACCP training for all plant

employees was conducted and documented.

2. HACCP Committee needs to change the document to clarify that prerequisite document monitoring does not have to be conducted by nationally trained personnel.
3. Record review takes a lot of time for the verifier, the in-house auditor, the state regulator and other third party auditors because of the organization and storage of the records as well as the centralization of the records and verification is primarily assigned to one individual.
4. The state listing audit and the state regulatory audits adequately and comprehensively address the plant sanitation requirements but fail to adequately evaluate the plant's HACCP System. Specifically, the audits failed to identify some deficiencies, non-conformities and organization of verification activities. The state HACCP audit reports indicated the state was inspecting the plant for floors, walls and ceilings rather than to audit against the plant HACCP system's ability to continuously assure dairy product safety.
5. The centralized approach to maintaining the HACCP written program, oversight and verification as practiced in this plant creates a burden on one individual. It may be a better use of plant resources to spread the responsibilities for training, records verification and HACCP program maintenance over the entire HACCP team. Freeing up the HACCP coordinator should allow more time to verify the system as a whole for complete implementation and thoughtful analysis.
6. HACCP team was divided into development and compliance teams; the evaluation team found this useful.
7. Plant stated that state demanded use of specific HA form that proved difficult to understand and state provided no assistance in filling out.
8. The prerequisite program and CCPs in the written HACCP program were written and implemented at an appropriate level of detail resulting in almost complete documentation and verification. Frequent HACCP written program updating resulted in some inconsistencies in terminology that create unnecessary difficulties for auditors. There were some minor inconsistencies in the written HACCP program and hazard analysis with prerequisite names, within products, between products with the same hazard profile and between the hazard analysis and prerequisite programs.
9. Both the state and FDA regulatory personnel expressed the opinion that a HACCP listing implies increased expectations beyond the traditional PMO program. The NCIMS HACCP Committee needs to clarify that the intent of the HACCP pilot is to provide an equivalent level of product safety, noting that there is a recognized potential under the HACCP pilot to achieve a higher level of assurance or confidence in the safety of the product which may result from increased documentation, verification, resources, regulatory presence, etc.
10. Does a person who verifies critical factors have to go to HACCP training when they are a certified supervisor?

HACCP Audits, Listing Procedures, and Follow-up Actions

Recommendations

1. Wording in the pilot document should be modified prior to insertion into the PMO, Section 3 to address link to Appendix K in the body of the PMO.
2. Address and clarify audit frequencies in Appendix K. (see Appendix K)
3. The Evaluation Team recommends that the NCIMS HACCP Committee include in its proposal wording to encourage the Executive Board to work with FDA to strengthen the use and frequency of the state program evaluation in order to support the uniformity and reciprocity provision of the NCIMS Program.
4. The HACCP Committee needs to provide direction to state regulators how to deal with repeat violations.

Findings

Mainly, the routine regulator is responsible for auditing the HACCP system although the listing officer and the regional milk specialist have less frequent roles.

1. The audit frequencies delineated in the HACCP document are confusing and need to be clarified.
2. There is a perception among some state and FDA regulatory personnel that HACCP plants are to be held to a higher standard of public health assurance, with increased expectations beyond the traditional program, rather than being a true alternative.
3. Some states did not implement the 6-month audit interval and the plant equipment testing provisions. This somewhat hindered the ability of the Evaluation Team to fully evaluate these provisions of the pilot although there were no obvious negatives encountered where they were implemented. It was noted that state regulators were in the plant often for purposes other than scheduled audits.
4. There was a question about how to deal with repeat violations from audit to audit and even what constituted a repeat violation.
5. One state used the HACCP Audit Verification Form found on the web site for the pre audit interview. This seemed to give the regulator a better basis to plan the regulatory audit.
6. Correction timelines were being used for the findings of most regulatory audits. They were being noted differently from state to state. Follow-up varied substantially in practice. Some states noted follow-up on the ensuing audit.
7. The audit form does not have a space to note that it is a follow-up audit.

Observations Note - These observations are very site and date specific, representing individual team member's observations. Individual observations were captured for further discussion and later evaluation by the complete Evaluation Team. Many of the observations are based on requirements listed in the plant's HACCP written program and are not requirements of the NCIMS HACCP pilot program.

1. How should the committee deal with repeat violations; answer is - same as existing system.
2. Question for committee-- how should the committee deal with repeat violations?
3. Should repeat violations result in a notice of intent to suspend?
4. Dealing with repeat violations should be added to audit form as a notice of intent to suspend.
5. Use of the regulatory summary sheet is a useful tool and we like it.
6. Protection from contamination marked 7of 7 times.
7. The HACCP Audit Verification form should be used for pre-audit interview.
8. Recommend that the committee change section 12 on audit form to reflect "previous audit findings corrected" so corrections and failures to correct will be documented on supplemental page.
9. All the recent state audits had correction timelines established.
10. Recommend that the Training Subcommittee recommend the HACCP Audit Verification form be used for pre-audit interview auditing.
11. Received goat milk at 47 ºF and held 33 hours before processing ending at 50ºF.
12. Plant not listed for goat milk on the listing audit and receives goat milk from unlisted source, we think
13. Priority for addressing problems that was high for state regulatory under traditional system now needs to be shifted to HACCP team verification. This shift has not occurred yet at this plant
14. The plant has very good documentation of most activities in HACCP. There are cases where it is hard to navigate the system because it is hard to move from one document to another. Improving the connections between documentation pieces should reduce verification time and regulatory time spent.
15. The HACCP Committee may want to include a box at the top of the audit form which lists the various types of audits and allows the user to check the applicable purpose of the audit.
16. The HACCP Committee may want to develop a summary sheet of observations and findings to be included with the audit report so the auditor has a place to put details of their findings and observations.
17. The level of commitment, oversight and auditing by the state auditor and state listing

officer demonstrate strong state regulatory oversight of the HACCP pilot plant, using advisory visits, corrective action time lines, and audit follow-up visits.

18. The over commitment of resources (maintaining four month audit frequencies and monthly plant visits) to monitor this HACCP pilot plant has caused the state regulatory agency to be very reluctant to participate with another volunteer HACCP pilot plant. The state has an opportunity to reduce the frequency and length of follow-up visits freeing resources based on the observations of the Evaluation Team. The state was not willing at this time to accept other plants into the HACCP pilot primarily because of resource limitations.
19. The Evaluation Team notes the intent of the state regulatory agency to upgrade its computerized dairy records system. The current computerized records system results in data summaries, which are less than complete and reliable. This creates difficulty in the evaluation of product and water sampling records.
20. Audit reports appeared to be well done and good follow-up but on wrong form (Phase I). Listing audit was done before Jan. 2002 training using Phase I form without attached flow diagram or product description. If the new Phase II form been used, observation regarding HTST #4 not included in HACCP program would have been considered a critical listing element.
21. Mold was noted in cottage cheese caused by condensate.

FDA State Program Evaluations & Follow-up Actions to be Taken

Recommendations

1. The HACCP Committee needs to better define the role of state program evaluation in order to ensure this element of the HACCP program fulfills its necessary function (The NCIMS Liaison Committee is evaluating the role and detail of state program evaluations for the traditional NCIMS program and will be making recommendations on HACCP state program evaluations.

Findings

The state program evaluations for the HACCP pilot have not been completed by FDA Regional Milk Specialists to make them available for the review by the Evaluation Team.

Observations - None

Acknowledgments

The evaluation committee wishes to acknowledge the participating pilot plants, state regulatory agencies and FDA in both Phase I and Phase II of the pilot. The commitment of the participants was considerable in both time and resources. The state and industry participants endured a heightened level of scrutiny as they had to produce and document programs and procedures, justify decisions, rewrite documents and commit to training. In addition these brave souls had to endure the imposition, questionnaires, and probing of an Evaluation Team determined to evaluate every aspect of implementation of the HACCP program. The participants accomplished this with grace and hospitality. The Evaluation Team salutes them for their contribution to the understanding of how this program should be implemented.

We wish to thank the NCIMS HACCP Committee for its guidance and moral support. Thanks also to the FDA for support of travel without which the team could not have conducted its evaluations.

The Team acknowledges the commitment of its members who donated their time, endured a summer of airports and hotels, late night evaluation sessions and innumerable conference calls and report revisions. We also wish to thank Richard Graham who came out of what could otherwise have been a peaceful retirement to encourage, cajole, and otherwise lead a diverse group of dairy industry professionals with a common mission.

Evaluation Team Members:

Richard Graham-Chairman	Dr. John Rushing	Randy Arbaugh
Steve Sims	John Beers	Dr. Bill Sveum
Allen Sayler		

Appendices

Appendix I.	Industry, State Auditor, State Rating Officer, State Program Administrator and FDA Regional Milk Specialist Questionnaires- Responses, and Summaries
Appendix II.	Listening Session Summary and Response
Appendix III.	Summary of Regulatory Information (Inspections, HACCP Audits, State Ratings, Pre and Post HACCP Evaluations, FDA Check-Ratings, Regulatory samples)
Appendix IV.	Positive Observations and Comments from Plant Visits

Appendix I.

Industry, State Auditor, State Rating Officer, State Program Administrator and FDA Regional Milk Specialist Questionnaires- Responses, and Summaries

Executive Summary

HACCP Pilot Phase I and II Participant Survey

Recommendations supported by the responses to these questionnaires were reviewed by the NCIMS HACCP Evaluation team and presented to the NCIMS HACCP Committee. All three groups of participants, industry, state regulators, and regional milk specialists stated that under the HACCP pilot, product safety was not adversely affected because they agreed there was equivalency between the traditional PMO system requirements and industry's implementation of HACCP.

The maximum score possible on the scored portion of the questionnaire was 5.0. Industry and the RMSs responded with an average score of (4.4) and the state regulators with an average score of (4.1) when asked if HACCP was equivalent to traditional controls. Industry comments reflected the positive impact of HACCP noted by improvements in plant sanitation (4.0) and corrective action programs (4.0), and reductions in withheld product (see attached Excel spreadsheets).

All participants agreed that monitoring of other NCIMS requirements they were accountable for was equivalent under the pilot, industry (4.6), state (4.3), and RMS (4.4). When asked if there was equivalency between the state HACCP listing and the traditional state rating or the FDA audit of the HACCP listing versus the traditional check rating the participants again agreed there was equivalency as noted in the summary table.

Industry responses were 4.6 and 4.1 respectively, state responses were 4.5 and 4.2, and the RMS rated the equivalency of the state HACCP listing to the traditional state rating with a score of 3.6 but rated the FDA audit of the HACCP listing to traditional check rating with a higher score of 4.2. These statements are made based on the fact that the responses were either agreed, strongly agreed or in a few instances no opinion was checked but there were no responses in either the disagree or strongly disagree category regarding the equivalency of the HACCP and traditional control programs.

Summary of responses to common questions asked of the industry, state, and RMS pilot plant participants in Phase I and II.

Question	Industry*	State*	RMS*
Equivalency of HACCP to traditional food safety plant controls	4.4	4.1	4.4
Plant monitoring of other NCIMS requirements under the pilot was equivalent	4.6	4.0	4.4
State monitoring of other NCIMS requirements under the pilot was equivalent	4.1	4.3	4.4
Equivalency of state HACCP listing/traditional state rating	4.6	4.5	3.6
Equivalency of FDA audit of HACCP listing to traditional check rating	4.1	4.2	4.2

*These statements are made based on the fact that the responses were either agreed to, strongly agreed to, or in a few instances no opinion was checked but there were no responses in either the disagree or strongly disagree category regarding the equivalency of the HACCP and traditional control programs. The response to each question was recorded using the following scale: (1-1.4) Strongly disagree, (1.5-2.4) Disagree, (2.5-3.4) No opinion, (3.5-4.4) Agree, (4.5-5) Strongly agree and in some cases () NA. The NA response has limited use.

Industry

The responses by the industry participants are supportive of the pilot. As stated in the executive summary benefits included decreases in plant sanitation deficiencies and improved corrective action programs. Several plants also noted their relationship with regulatory groups improved as a result of their participation in the pilot. Several of the industry participants felt implementation of the pilot had significant impact on their individual job responsibilities and sites required additional resources for training under the pilot.

One major concern with the response by the industry pilot participants, though, is their understanding of the significance of hazards. Many responded to the question “were additional hazards identified” by listing dead end piping, piping changes, O rings, rusted seals, and washer coolers. While the improvements are important changes to a manufacturer’s sanitation and maintenance programs, they are not hazards from the HACCP context of biological, physical, and chemical hazards. The HACCP Pilot Team will need to address this misunderstanding either through training materials or possibly posting a question to the technical resource team. One site did note the manufacture of eggnog for inclusion in its hazard analysis.

Examples of industry comments include:

- “Operators more cautious and thorough”
- “Because of HACCP, a number of opportunities have opened up for us including air

blows, improved shelf-life for non-Grade "A" products, etc"

- "Unify government then implement HACCP w/industry input and justify what is required by scientific data for both the regulatory and industry"

- "Involve more upper management in initial training to help fully understand what is involved"

- "State has more confidence we can't hide anything"

We also asked the participants what costs they incurred implementing HACCP. Costs reported ranged from $150,000 to $2,000 but on average without the high and low responses it was indicated that HACCP implementation could be accomplished with an investment of $20,000 dollars for the average plant. Implementation hours again had the same extreme range but training averaged 100 hours for most plants. Significant time commitments were made to corrective action and verification activities.

State Regulators

Scores on the questionnaires support the executive summary finding that respondents believe public health under HACCP was not compromised. For example the following comments reflect the lower scored or no opinion responses to questions on equivalency:

- "I believe that HACCP gives the perception that a plant is better than the Grade A traditional system".

- "I believe the best way to make HACCP the very best Grade A system – is to make the Prerequisite Program mandatory in the traditional Grade A system. Allow regulatory to monitor the PP's, make mandatory employee training and give the inspector the obligation to quiz employees on their job knowledge. This would marry the best of HACCP with the PMO (greatest public health document in existence for dairy)".

- "A plant under HACCP could evaluate that no public health hazard existed using all Grade A traditional laboratory analysis and accept ungraded (R.O.) milk for Grade A products. This is a possibility under the HACCP guidelines". Editors Note*:* The traditional system and the HACCP pilots required all milk to originate from a Grade A listed source.

- "My personal experience with the HACCP Audit is that a score should be given on the audit form. This would allow for a plant that has a lot of verbiage on an audit to know its place value. I believe this would keep a plant from ignoring PP's and only worrying about CCPs, by giving PP a point value it would give more significance to them as a deficiency. I do not believe that a plant who corrects problems as the audit is ongoing should not be subject to a failing score and or delisting. If we allow plants to make corrections as the audit is ongoing we have done nothing to protect public health the day after we leave the plant and then for the next four months (some States 6 months)".

Positive statements regarding HACCP were also made:

- "Total understanding of the plant process and flow, open communication between plant and regulatory. HACCP puts the responsibility on the plant and regulatory as an overseer".

- "Due to the extensive hazard analysis I was able to better understand the complex processing of milk and milk products".

- "It focuses on each step of a product process. It better documents the steps of the process".

- "HACCPs strongest edge over the traditional Grade A system is that HACCP requires that the rules (PP's) be written down. This allows the plant to remove interpretation and to train their employees consistently every time. If the HACCP plan is written properly with all pertinent manufacturing operations included this can be used as a training manual for all new and present employees".

- "The program needs some good press. It needs to be understood that HACCP is a total commitment for both regulatory and industry. HACCP take time. More time is spent on record review then actual plant inspection".

Regional Milk Specialists

The average scores for equivalency and adequate public health protection (under the pilot) by the RMSs were actually higher than those submitted by industry. This position is reflected in the executive summary. The industry participants actually scored some of the same questions slightly lower but there is no significant difference between the two groups of pilot participants. The MSS also responded positively with a rating of 4.2 for the following question, "Under the NCIMS HACCP Pilot, the Regulatory Agency is able to verify and assure the safety of Grade A milk products from a milk plant at least as well as they could under the traditional system"?

However, there were wide differences of opinion between the RMSs that submitted written responses to the question, "What is the greatest benefit of the HACCP pilot"? This ranged from, "I have as yet not seen any benefit" to "The greatest benefit is that you can witness what the plant is doing during the times that there is no outside overview of how the plant operates. We can now understand how the plant is actually operating". In that regard the RMS that had not seen any benefit from HACCP submitted the lowest scores in reference to the pilot.

Background: Summary of HACCP Pilot Questionnaire Evaluations

The attached charts and summaries detail the responses of industry participants (all twelve plants participating in Phase I or II responded), state regulators (all states participating in the pilot had regulatory representatives respond to the questionnaire but the number of State Directors, listing officers or rating officers varied), and regional milk specialists (all five involved in the pilot) working with the pilot plants. The three groups

were asked common questions as well as questions unique to their role as a manufacturer, state regulator, or RMS. Examples of each questionnaire are attached for review. The summary of the surveys was been blinded by removing any reference to the manufacturing site or brand names, FDA region, or state that had regulatory oversight for the specific pilot plant. The response to each question was recorded using the following scale:

(1) Strongly disagree
(2) Disagree
(3) No opinion
(4) Agree
(5) Srongly agree
and in some cases () NA. The NA response has limited use.

The responses to each question were averaged. A high or low average score must be interpreted in context of the question. Whenever the three groups were asked a common question those results were also compared to determine the degree of agreement among the HACCP pilot participants. Comments by the three groups that responded to the questionnaire are addressed separately.

Attachments

1. Summary of HACCP pilot questionnaires for all participants
2. Industry questionnaire
3. State regulatory Program Director's questionnaire
4. State regulatory Milk Plant Regulatory Auditor's questionnaire
5. State regulatory State Listing Officer's questionnaire
6. Regional Milk Specialist questionnaire

Attachment 1.
Summary of HACCP Pilot
Questionnaires for all participants

Milk Plant Responses to Scored Questions Participated in both the Phase I & II Pilots*						
Question	**Plant 1**	**Plant 2**	**Plant 3**	**Plant 4**	**Plant 5**	**Average**
1. Equivalency of HACCP to traditional plant controls	4	4	4	5	4	4.2
2. Was product safety monitored more completely under HACCP	4	4	4	4	4	4.0
3. Regulatory verification is equivalent under HACCP	4	5		5	4	4.5
4. State HACCP listing was equivalent to traditional listing	4	4	4	5	5	4.4
5. Product shelf life increased	2	3	3	4	3	3.0
6. Consumer complaints decreased	4	3	3	3	3	3.2
7. Withheld product decreased	4	3	4	3	3	3.4
8. Sanitation monitoring results improved	4	4	5	5	4	4.4
9. FDA audit of HACCP listing was equivalent to traditional check rating	5	4	4	5	4	4.4
10. Plant monitoring of other NCIMS requirements are equivalent	4	4	5	5	4	4.4
11. State and FDA monitoring of other NCIMS requirements is equivalent	4	4		5	4	4.3
12. Corrective action programs improve under the HACCP pilot	4	4	4	5	5	4.4
13. HACCP pilot had no impact on my job responsibilities	2	1	1	1	4	1.8
14. HACCP listing reduced requests for third party audits		5	4	3	4	4.0
15. Relationship with state regulator improved under the pilot	2	4	3	5	3	3.4
16. Relationship with FDA regulator improved under the pilot	4	4	5	4	4	4.2
17. Volunteering for the HACCP pilot was the right thing to do	4	3	5		4	4.0
18. Use of a HACCP consultant was beneficial		3		4	2	3.0
19. NCIMS Technical Assistance Team was valuable	4	4	5	4	4	4.2
20. Volunteering for the pilot was a sound decision	5	4	5		4	4.5

*Note: All plant designations have been randomized between tables so Plant #1 in this table is not the same as Plant #1 in other tables.

Milk Plant Responses to Scored Questions Participated in Phase II Pilot only*								
Question	**Plant 1**	**Plant 2**	**Plant 3**	**Plant 4**	**Plant 5**	**Plant 6**	**Plant 7**	**Average**
1. Equivalency of HACCP to traditional plant controls	5	4	4	4	5	5	5	4.6
2. Was product safety monitored more completely under HACCP	5	2	4	4	5	5	5	4.3
3. Regulatory verification is equivalent under HACCP	5	4	4	4	5	5	5	4.6
4. State HACCP listing was equivalent to traditional listing	5	4	4	4	5	5	5	4.6
5. Product shelf life increased	2	2	3	2	4	4	3	2.9
6. Consumer complaints decreased	2	3	3	2	4	3	3	2.9
7. Withheld product decreased	2	2	3	4	4	3	3	3.0
8. Sanitation monitoring results improved	4	2	3	4	5	4	4	3.7
9. FDA audit of HACCP listing was equivalent to traditional check rating		4	4			3		3.7
10. Plant monitoring of other NCIMS requirements are equivalent	5	5	5	4	5	5	5	4.9
11. State and FDA monitoring of other NCIMS requirements is equivalent	5	2	5	4	5	5	3	4.1
12. Corrective action programs improve under the HACCP pilot	2	2	4	4	5	5	4	3.7
13. HACCP pilot had no impact on my job responsibilities	1	4	2	1	2	2	1	1.9
14. HACCP listing reduced requests for third party audits	3	3	5	4	5	3	4	3.9
15. Relationship with state regulator improved under the pilot	1	3	3	1	4	2	3	2.4
16. Relationship with FDA regulator improved under the pilot	2	2	5	4	4	4	4	3.6
17. Volunteering for the HACCP pilot was the right thing to do	2	4	3	4	4	3	3	3.3
18. Use of a HACCP consultant was beneficial		4	5			3		4.0
19. NCIMS Technical Assistance Team was valuable		4		5	5	3		4.3
20. Volunteering for the pilot was a sound decision	4	5	5	4	5	5	4	4.6

*Note: All plant designations have been randomized between tables so Plant #1 in this table is not the same as Plant #1 in other tables.

Plant Personnel that participated in both Phase I and Phase II Pilots
How would you improve the program?
I'll think more about this before your visit. I personally think the pilot has gone very well. We have been fortunate to have support from regulatory officials who are willing to be ahead of the curve and try something new. Although there have been challenges along the way, in hindsight I think our plant has succeeded with HACCP and any challenges were worth it when we see the end result which has been increased employee buy in and product that is at least as safe as it was under the PMO.
Unify government then implement HACCP w/industry input and justify what is required by scientific data for both the regulatory and the industry
Plant HACCP team believes that the NCIMS HACCP pilot program has been conducted very well
Because of HACCP, a number of opportunities have opened up for us including air blows, improved shelf life for non- Grade "A" products, etc.
I would like to comment on question 17. I do not know if we would have volunteered for the Pilot Program if we knew our plant would be under going so many changes. The positive thing about XXXX participating in the Pilot would be that we have develop a strong HACCP Program and our associates are better trained and understand how their job affects food safety and we accomplished this while our Plant was going through personnel and construction changes. I believe this says a lot for our Plant and associates plus sets the standard that HACCP can be done and done well through adverse conditions. Looking back to the beginning of the Pilot to now, I am very pleased with our decision to participate in the Pilot and would encourage others to choose HACCP over the traditional system.
I would like to address the hours in E. The hours are stated to reflect the amount of time invested per incident. The HACCP team and I perform verification on a quarterly basis. The entire team does not devote 20 hours – most of that time to me but they spend about 8 hours. The yearly validation is a more extensive review of the HACCP document with the team. Also, the hours for training are not accurate. HACCP is part of our associates' job description so they are trained initially on the concept of HACCP then it's continuous. Our new associates do not know what it was like before HACCP or how their job description has changed. Much of the time was for associate training.
The only suggestion I would make concerning how to improve the program would be to have clearer guidelines and better communication. I know a lot of issues have been dealt with in Phase II but I think more structure needs to be given as far the program.
Make guidelines clearer and more specific in key areas so less confusion and more direction in beginning. Give people ideas and suggestions and acceptable control measures for consistency across the industry. Examples of forms and documentation would also be helpful.
Because of HACCP, plant experienced increased flexibility that resulted in operational efficiencies that contributed to plant operation, product safety and product quality.
Provide more specific and detailed information on verification and validation.
No comment

Plant Personnel that participated in both Phase I and Phase II Pilots
How would you improve the program?
More direct help from NCIMS or IDFA at each plant or better examples.
Regulatory agencies from different states should work together and share experience and knowledge.
One five-day HACCP course is not enough. Why not do two five-day workshops approx. 4 – 6 month apart. The second workshop could be done in small groups by plant and the plant team should present their HACCP work to the experts.
Un-experienced regulators should not do listing audits; NCIMS should get one expert involved.
The Baltimore training was good but as an initial training for someone with no background in HACCP I think it went a bit too fast. It would have been helpful to have reviewed the training material before the session. Also I feel that in order to assist plant to get up and running. An onsite visit by someone with HACCP training would be most helpful. We had Steve Pierson visit in May. He gave us important direction and guidance that got us much more quickly along than if we plodded along on our own.
Involve more upper management in initial training to help fully understand what is involved

Milk Plant Responses Estimated Resources, Phase I & II Plants*						
HACCP training	**Plant 1**	**Plant 2**	**Plant 3**	**Plant 4**	**Plant #**	**Average**
HACCP team	84 hrs.	600	2 hrs./mo.	8	100	198.0
Production Personnel	6	400	1 hrs./mo.	2		136.0
45 day audit prep	20	500	32			184.0
4 month audit prep	28	500	32	30		147.5
Verification activities	520	5,200	5 hrs./wk.	20		1913.3
State Program Evaluation by FDA		200				200.0
Other (audits since initial 4 month audit)	58					58.0
Other (Correcting deficiencies identified				1,800		1800.0
HACCP Document Preparation	60	600	1 day/wk.			330.0
Baseline Survey	8	300	1 day/wk.	20		109.3
Advisory Visit's) by State & FDA	12	300	16	20		87.0
State Listing Audit's)	32	400	32	30		123.5
FDA Check Audit (Prep. & Audit	28	300	32	50		102.5
Validation Activities	12	200	1 day/wk			106.0
HACCP Written Program Review & Updating	30	2,000	120	40		547.5
Did the Hazard analysis change since the initial listing?	Yes	Yes	No	Yes	Yes	
Costs for HACCP Implementation	$5,200	$150,000	$10,000	$24,000	$10,000	$39,840

*Note: All plant designations have been randomized between tables so Plant #1 in this table is not the same as Plant #1 in other tables.

Milk Plants Estimated Resources, Phase II *								
HACCP training	**Plant 1**	**Plant 2**	**Plant 3**	**Plant 4**	**Plant 5**	**Plant 6**	**Plant 7**	**Average**
HACCP team	3 hours	100	120	100	120	400	65	129.7
Production Personnel	3	80	3	10	80	70	40	40.9
45 day audit prep			6	12	36	15		17.3
4 month audit prep				12		5		8.5
Verification activities	10	50	120	48	180	200	2	87.1
State Program Evaluation by FDA				48				48.0
Other (audits since initial 4 month audit)								
Other (Correcting deficiencies identified	10	20	50	24		10		22.8
HACCP Document Preparation	100	100	150	200	180		300	171.7
Baseline Survey	16	8		3	12	20	16	12.5
Advisory Visit's) by State & FDA	20	20		50	36		36	32.4
State Listing Audit's)	16	14	12	144	30	20		39.3
FDA Check Audit (Prep. & Audit				0				0.0
Validation Activities		20		16		4		13.3
HACCP Written Program Review & Updating		50		8	72	6	100	47.2
Did the Hazard analysis change since the initial listing?	No	No	No	No	No	Yes	NA	
Costs for HACCP Implementation (Dollars)	Unknown	$12,500	$2,000	$50,000			$20,000	$21,125

*Note: All plant designations have been randomized between tables so Plant #1 in this table is not the same as Plant #1 in other tables.

FDA Milk Specialists Response to Scored Questions - Phase I & II Pilots*						
Question	**RMS 1**	**RMS 2**	**RMS 3**	**RMS 4**	**RMS 5**	**Average**
1. Equivalency of HACCP Listing/FDA check rating	4	3	4	5	5	4.2
2. Equivalency of plant control/traditional system	4	4	4	5	5	4.4
3. Ability to verify safety under HACCP/traditional	4	3	4	5	5	4.2
4. Equivalency of state HACCP listing/traditional state rating	4	3	4	5	2	3.6
5. State monitoring of other NCIMS requirements under pilot	4	4	4	5	5	4.4
6. Plant monitoring of other NCIMS requirements under pilot	4	4	4	5	5	4.4
7. Equivalency of state HACCP listing/traditional listing	4	4	4	5	5	4.4
8. Adequacy of Baltimore HACCP training	4	4	4	5	4	4.2

*Note: All RMS have been randomized between tables so RMS #1 in this table is not the same as RMS #1 in other tables.

FDA Milk Specialists Estimated Hours, Phase I & II Pilots*						
	RMS 1	**RMS 2**	**RMS 3**	**RMS 4**	**RMS 5**	**Average**
Baseline survey	16	16				16
Advisory visit(s) to milk plant	24	8			64	32
4 month audits				108		108
FDA Audits	24			33		28.5
State listing audit		12		48		30
State program evaluation		40				40

*Note: All RMS have been randomized between tables so RMS #1 in this table is not the same as RMS #1 in other tables.

FDA Milk Specialists that participated in both Phase I and Phase II Pilots
Greatest benefit
The greatest benefit that I have seen is the reaffirmation of food safety by the management of the pilot plant.
Benefit—I have as yet not seen any benefit.
Working together with the plant personnel and state regulatory personnel from the very beginning. We all learned together and it appeared to work successfully the pilot site and was thus, a positive experience.
The greatest benefit is that you can witness what the plant is doing during the times that there is no outside overview of how the plant operates. We can now understand how the plant is actually operating.
HACCP is a more relevant state enforcement model. The HACCP process is more consistent with the traditional inspectional and training activities of SRO and RMS.
Greatest concern
My greatest concern is that the HACCP pilot program will continue to be expanded & extended at the 2003 NCIMS. Please let me explain.
My concern actually stems from what I see as a trend in the NCIMS and was actually brought to light while attending a meeting on Automated Milking Systems. First off, I believe that we (FDA) dropped the ball in allowing milk produced in this pilot program (AMS pilot) to be marketed as Grade A. The speaker stated that there might be a proposal to expand & extend the AMS pilot. I see this as an attempt to set precedents. Extending & expanding this pilot will continue to allow milk of questionable quality to be marketed as Grade A, thereby setting a precedent to argue against any objection by FDA. (The milk was Grade A for the pilot, therefore it is Grade A now)
Please don't misunderstand me. I have a tremendous appreciation of the vast amount of work that has been done on the HACCP pilot and I am not accusing the HACCP pilot of any wrongdoing. Allowing any pilot to expand and or extend conference-to-conference is similar to having a toe then foot then leg in the door. I hope that this is something that we consider in the future prior to agreeing to pilot programs. A <u>firm</u> deadline should be set by the NCIMS for the submission of data and pilot evaluations.
Personnel changes at the facility, or a change in plant motivation could put the program at risk.
The concern is that the plant is not keeping accurate records of the problems and corrections that they are making. For the most part they are making the corrections properly and timely but there is no record to show what was done to make the correction and how to prevent it from happening again. (This has been extensively better in the last six months.) The other concern is that it takes the plant too long to get into the dairy HACCP mode after they have started up. I think most of the plants are already doing the correction items, but have never followed it through to look at what they are doing.
No comment
No comment
Suggestion for improving the HACCP pilot
The HACCP committee has spent a great deal of time trying to formulate a rating/check rating system for HACCP. Farms that are regulated by the Performance Based Inspection System are rated & check rated under the traditional system. I believe that HACCP plants could be

regulated by States under HACCP but rated & check rated under the traditional system. I believe that the states would accept a proposal such as this
I believe that HACCP is a very beneficial tool that industry should use to enhance product protection.
Training is the single most important ingredient for FDA, State and Industry alike in order for HACCP to be a viable alternative to the traditional system. Many states at this juncture have had minimal exposure to HACCP. They will be getting some training through juice HACCP. I have had some recent conversations with some states in our region that want some exposure. To conducting a HACCP audit. During the 510 courses in XXXXX last week some preliminary plans were made to have some members of the XXXXX Dairy Division receive some Training in XXXX.
Making a basic model of the way for the plants to track deviations, showing corrections, and prevention of the event happening. That seems to be one of the difficult parts of the HACCP system for plants to grip. The other is that the prerequisites need to be emphasized a lot more as the plant is starting up.
As a regulatory model – nothing. As a rating and listing model an enforcement rating is needed. States are responsible for permitting, sampling, interpretation, inspection, pasteurization testing (salt), enforcement, and records. These items are not captured in the HACCP listing.

State Regulatory Auditors
Responses to Scored Questions, Phase I & II Pilots*

Question	State 1	State 2	State 3	State 4	State 5	Average
1. Equivalency of listing audits/traditional inspection		4	4	5	5	4.5
2. Equivalency of plant control/traditional system	5	4	4	4	5	4.4
3. Equivalency of state HACCP listing/traditional state rating	5	3	4	5	5	4.4
4. Equivalency of HACCP Listing/FDA check rating	5	3	4	3	5	4.0
5. State monitoring of other NCIMS requirements under pilot	5	4	4	4	5	4.4
6. Plant monitoring of other NCIMS requirements under pilot	4	3	4	4	5	4.0
7. FDA/listing officer monitoring of other NCIMS requirements under pilot	5	4	4	3	5	4.2

*Note: All states have been randomized between tables so State #1 in this table is not the same as State #1 in other tables.

State Regulatory Auditors Responses to Scored Questions, Phase II Pilot*			
Question	**State 1**	**State 2**	**Average**
1. Equivalency of listing audits/traditional inspection	4	3	3.5
2. Equivalency of plant control/traditional system	4	1	2.5
3. Equivalency of state HACCP listing/traditional state rating	4	1	2.5
4. Equivalency of HACCP Listing/FDA check rating			
5. State monitoring of other NCIMS requirements under pilot	4	1	2.5
6. Plant monitoring of other NCIMS requirements under pilot	4	1	2.5
7. FDA/listing officer monitoring of other NCIMS requirements under pilot	4	1	2.5

*Note: All states have been randomized between tables so State #1 in this table is not the same as State #1 in other tables.

State Regulatory Auditors Time Required, Phase I & II Pilots*					
Question	**State 1**	**State 2**	**State 3**	**State 4**	**Average**
Baseline survey			8		8.00
Advisory visits to plant			12		12.00
State listing audits	24		8	24	18.67
4 Month Audits	24	43.5	38	8	28.38
"Follow-up" Audits	2		4		3.00
FDA Audit	24		16		20.00

*Note: All states have been randomized between tables so State #1 in this table is not the same as State #1 in other tables.

State Regulatory Auditors Time Required, Phase II Pilots*					
Question	**State 1**	**State 2**	**State 3**	**State 4**	**Average**
Baseline survey	64		12	8	28.00
Advisory visits to plant	9		170	12	63.67
State listing audits			54	8	31.00
4 Month Audits			205	38	121.50
"Follow-up" Audits			24	4	14.00
FDA Audit		4	30	16	25.00

*Note: All states have been randomized between tables so State #1 in this table is not the same as State #1 in other tables.

State Regulatory Auditors that participated in both Phase I and Phase II Pilots
Greatest benefits
I see the greatest benefit as more responsibility for the plant-it get them more involved in the safety of the products they produce
My greatest benefit and I believe HACCP's best asset is that the RULES (PP's) are all written down this allows regulatory and all plant persons to know and understand the "maintenance" of the manufacturing plant. For example: the life expectancy of air filters, instead of waiting for the filters to clog up we now change them on a timely interval. CIP and COP chemical strengths are now listed and monitored, this keeps us from reacting to dirty equipment because the operator did not know or understand their Chemical strengths.
I had to take a closer look at how the plant operates and functions which leads to better audits.
Educational component ensures company-wide dialogue/practices
Greatest concern
My greatest concern is the addition of yet another HACCP style, we've already got USDA HACCP, FDA and National Marine Fisheries Seafood HACCP, juice HACCP, health department HACCP, corporate audit HACCP
I believe that HACCP gives the perception that a plant is better than the Grade A traditional system.
My greatest fear is that we will begin to monitor records more than we physically monitor the plant and equipment. We have already found issues with the plant having trouble with record keeping and that the record keeping is requiring an additional person to keep up with these records. I believe that a small plant might remove a person from the manufacturing operation and make this person responsible for record keeping.
Integrity and cooperation of plant employees is a must.
Concerned about manpower issues when key personnel are called away for HACCP

Suggestions for improving HACCP as voluntary alternative to the traditional system
Provide a hazard guide and regularly scheduled HACCP training for regulatory and industry folks, since they are frequently using HACCP already as a corporate tool and for juice HACCP- I expect they're just waiting for the outcome of the pilot project to participate
My personal experience with the HACCP Audit is that a score should be given on the audit form. This would allow for a plant that has a lot of verbiage on an audit to know its place value. I believe this would keep a plant from ignoring PP's and only worrying about CCPs, by giving PP a point value it would give more significance to them as a deficiency. I do not believe that a plant who corrects problems as the audit is ongoing should not be subject to a failing score and or delisting. If we allow plants to make corrections as the audit is ongoing we have done nothing to protect public health the day after we leave the plant and then for the next four months (some States 6 months).
I believe the best way to make HACCP the very best Grade A system – is to make the Prerequisite Program mandatory in the traditional Grade A system. Allow regulatory to monitor the PP's, make mandatory employee training and give the inspector the obligation to quiz employees on their job knowledge. This would marry the best of HACCP with the PMO (greatest public health document in existence for dairy).
For HACCP to be successful it must be a bottom up approach. Plants must be able to write their HACCP plan with as little input as possible from regulatory. There must be some items which regulatory must require but the plants need some leniency as to how to accomplish these items.
I believe the program is going well as is, at least until I have a chance to work with more plants.

State Regulatory Auditors that participated in both the Phase II Pilots
Greatest benefits
It focuses on each step of a product process. It better documents the steps of the process.
Greatest concern
This program may become mandatory.
Having to run a dual program
Initial record keeping. Plants may tend to "over demand" records of themselves. (i.e. in the prerequisite programs, etc.)
Suggestions for improving HACCP as voluntary alternative to the traditional system
Simplify
The plant I inspect is interested in doing some or all of its own HTST testing. More guidance/information should be provided (i.e. standardized training? Annual training for plant personnel? A new license? Etc?

State Milk Program Director *Responses to Scored Question - Phase I & II Pilot**			
Question	**State 1**	**State 2**	**Average**
1. Equivalency of listing audits/traditional inspection	5	4	4.5
2. Equivalency of plant control/traditional system	5	3	4.0
3. Equivalency of state HACCP listing/traditional state rating	5	4	4.5

*Note: All states have been randomized between tables so State #1 in this table is not the same as State #1 in other tables.

State Milk Program Director **Responses to Scored Questions - Phase II Pilot***				
Question	**State 1**	**State 2**	**State 3**	**Average**
1. Equivalency of state, FDA audits under pilot/traditional inspections/ratings	5	4	4	4.3
2. Equivalency of state NCIMS HACCP listing/traditional state rating	4	4	4	4.0
3. Equivalency of state monitoring of other NCIMS requirements under pilot	4	5	4	4.3

*Note: All states have been randomized between tables so State #1 in this table is not the same as State #1 in other tables.

State Milk Program Directors **Time Estimate in Hours - Phase I & II Pilot***		
Time Required in hours	**State 1**	**Average**
Baseline survey		
Advisory visits to plant		
State listing audits		
4-month audits	24	24
"Follow-up" audits		
FDA Audit		

*Note: All states have been randomized between tables so State #1 in this table is not the same as State #1 in other tables.

State Milk Program Directors Time Estimate in Hours – Phase II Pilot*			
Time Required in hours	**State 1**	**State 2**	**Average**
Baseline survey	64		64.0
Advisory visits to plant	9		9.0
State listing audits			
4 Month Audits			
"Follow-up" Audits			
FDA Audit		4	4.0

*Note: All states have been randomized between tables so State #1 in this table is not the same as State #1 in other tables.

State Program Director Comments Phase I & II Pilots
Suggestions for improving HACCP as voluntary alternative to the traditional system
Implement a scoring system for audits. Regulators are comfortable with a scoring system and it will improve the credibility of and usefulness of the audit.
Use 4-month audit intervals (rather than 6-month) to keep auditors from being overwhelmed
Most important suggestion to improve HACCP as a voluntary alternative to the traditional system
Don't dismantle the traditional inspection system. Maintain it as a safety net. Allow state regulators the option of a traditional inspection whenever they feel that one is necessary or warranted.

State Rating (Listing) Officers Response to Scored Questions - Phase I & II Pilots*						
Question	**State 1**	**State 2**	**State 3**	**State 4**	**State 5**	**Average**
1. Equivalency of listing audits/traditional inspection	5	4	5	4	5	4.6
2. Equivalency of plant control/traditional system	5	4	5	4	5	4.6
3. Equivalency of state HACCP listing/traditional state rating	5	2	5	4	5	4.2
4. Equivalency of HACCP Listing/FDA check rating	4	3	5	4	5	4.2
5. State monitoring of other NCIMS requirements under pilot	5	4	4	4	5	4.4
6. Plant monitoring of other NCIMS requirements under pilot	5	4	4	4	5	4.4
7. FDA/listing officer monitoring of other NCIMS requirements under pilot	4	3	4		5	4.0

*Note: All states have been randomized between tables so State #1 in this table is not the same as State #1 in other tables.

State Rating (Listing) Officers Response to Scored Questions - Phase II Pilots*			
Question	**State 1**	**State 2**	**Average**
1. Equivalency of listing audits/traditional inspection	5	5	5
2. Equivalency of plant control/traditional system	5	4	4.5
3. Equivalency of state HACCP listing/traditional state rating	5	5	5
4. Equivalency of HACCP Listing/FDA check rating	5	5	5
5. State monitoring of other NCIMS requirements under pilot	5	5	5
6. Plant monitoring of other NCIMS requirements under pilot	5	5	5
7. FDA/listing officer monitoring of other NCIMS requirements under pilot	5	5	5

*Note: All states have been randomized between tables so State #1 in this table is not the same as State #1 in other tables.

State Rating (Listing) Officers Time Required - Phase I and Phase II Pilots*						
Time required for Phase II (hours)	**State 1**	**State 2**	**State 3**	**State 4**	**State 5**	**Average**
Baseline survey						
Advisory visits to plant						
State listing audits	24					24
FDA Audit	24			24		24
Time required for Phase I (hours)						
Baseline survey	16					16
Advisory visits to plant	30					30
State listing audits	32					32
FDA Audit	24		93			58.5

*Note: All states have been randomized between tables so State #1 in this table is not the same as State #1 in other tables.

State Rating (Listing) Officers Time Required - Phase II Pilot*			
Time required for Phase II Hours	**State 1**	**State 2**	**Average**
Baseline survey	30	20	25
Advisory visits to plant	88	30	59
State listing audits	48	20	34
FDA Audit			

*Note: All states have been randomized between tables so State #1 in this table is not the same as State #1 in other tables.

State Rating (Listing) Officers that participated in both Phase I and Phase II Pilots
Greatest benefit
Benefits-total understanding of the plant process and flow, open communication between plant and regulatory. HACCP puts the responsibility on the plant and regulatory as an overseer.
I suppose the greatest benefit derived, from a regulatory standpoint, is the opportunity to actually participate in the formation and implementation of an authentic HACCP plan in a processing plant.
Greatest benefit is the plants (employees) increased understanding of process and procedures
Due to the extensive hazard analysis I was able to better understand the complex processing of products made at this facility.
Greatest concern
Time to complete audits
My primary concern centers around the important decisions the HACCP Committee will make in the next few months. Dairy HACCP will only be as successful as the regulatory criteria established to monitor its success or failure in each facility.
Greatest concern is amount of time involved
I was, and remain concerned this program will as cumbersome and "command and control" as the USDA FSIS counterpart.
Suggestions for improving HACCP **as voluntary alternative to the traditional system**
The program needs some good press. It needs to be understood that HACCP is a total commitment for both regulatory and industry. HACCP take time. More time is spent on record review then actual plant inspection.
Mandate the regulatory structure currently used with the traditional system and a state audit frequency of once each four months. Our experience in the pilot program has demonstrated that the traditional regulator structure blends very well with HACCP and the four month frequency allow our agency to stay in touch with changes in operation and address problems in a more timely manner.
In addition, I would suggest a scoring system be developed that would encourage a more uniform application in auditing from state to state. A scoring system would also place a value on prerequisite programs that does not currently exist.
Regulatory side-audit form is hard to work with and more training in doing HACCP audits
Submit the program for approval and implementation n the 2003 NCIMS conference. Set a deadline for XXX to start or withdraw their interest in phase II of the pilot.

State Rating (Listing) Officers that participated in the Phase II Pilot
Greatest benefit
Benefit-the auditor has the latitude to return and observe all aspects of a plant including training, etc.
By integrating a HACCP system, I see plant management and employees thoroughly involve in collecting data that serves to mentor the safety of their products. I see employees receiving training s in HTST pasteurization so that they recognize a problem that they probably would not have notice under the traditional system. Through their HACCP involvement, I see commitment form the plant management to all issues that we consider of vital importance as regulators.
Greatest concern
My greatest concern is that the initial momentum that it has taken to implement HACCP in the milk plant must be sustained. In other words, this HACCP approach must remain a way of life for the milk plant management and employees and be prioritized above all other responsibilities.
Suggestions for improving HACCP as voluntary alternative to the traditional system
It must be stated that some plants are ready for HACCP, some never will be. Those that are ready and can run better and more safely under a HACCP plan should be allowed to operate under HACCP.
I believe that we need continual training and evaluation: we need to implement a certification program for those of us who are performing HACCP listing audits; a completed Hazards Guide reference would represent an immediate improvement in the current HACCP alternative.
I believe that we need continual training and evaluation: we need to implement a certification program for those of us who are performing HACCP listing audits; a completed Hazards Guide reference would represent an immediate improvement in the current HACCP alternative.

Attachment 2. Industry Questionnaire

NCIMS HACCP EVAULATION TEAM
PILOT PLANT QUESTIONNAIRE

The NCIMS HACCP Evaluation Team will be visiting each dairy plant involved in the NCIMS HACCP Pilot Program between mid-May 2002 to the end of October 2002. For the Evaluation team to maximize its efficiency, we request the following survey be filled out and returned to Allen Sayler, International Dairy Foods Association at asayler@idfa.org or faxed to 202-331-7820. All survey information will be compiled into one report with confidentiality maintained so no one individual or plant can be identified. Thank you for your cooperation.

A.
Plant Name _____Person Completing Survey & Title _____
Phone Number _____ FAX _____ Email _____
Plant Manager _____ Plant HACCP Team Leader _____

B. Products Covered by the HACCP System (check all that apply):

- Fluid Milk (white or flavored)
- Cottage cheese
- Dried products
- Cultured (yogurt, sour cream, buttermilk)
- Aseptic Products
- Ice Cream Products
- Other (e.g. Butter, Ice Cream, Condensed Products, etc. – please list)

C. Attach list of HACCP Team Members Name, Title, & HACCP experience.

D. Listed below are statements and beneath each statement are five possible responses. Based on your experiences during the NCIMS HACCP Pilot, please mark the response that most closely reflects your opinion regarding each statement. ***During the onsite visits by the NCIMS Evaluation Team, you will have an opportunity to provide your reasons for, and comments about your responses.***

1). Under the NCIMS HACCP Pilot, we are able to monitor and assure the safety of Grade A dairy products we produce at least as well as (or better than) we were able to do under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

2). We now monitor the safety of Grade A dairy products we produce more completely under the NCIMS HACCP Pilot than we did under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

3). Under the NCIMS HACCP Pilot, the Regulatory agency is able to verify and assure the safety of Grade A milk products from our milk plant at least as well as they could under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

4). The current State NCIMS HACCP listing provides at least as much verification and assurance of the ongoing safety of Grade A milk products from my plant as did State Ratings made under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

5). Under the NCIMS HACCP pilot, Grade “A” products increased in product shelf life?
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

If shelf life increased, what was the per cent increase? _____

6). Under the NCIMS HACCP pilot, we had fewer consumer complaints.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

7). Under the NCIMS HACCP pilot, we had a decrease in withheld or nonconforming product.

( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

8). Under the NCIMS HACCP pilot, we observed constantly improved sanitation monitoring results.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

9). The latest official FDA audit of the HACCP listing for my plant provides at least as much verification and assurance of the ongoing safety of Grade A milk products from my plant as FDA check ratings have done under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree ( ) NA

10). “Other” NCIMS requirements, such as, Appendix N drug monitoring, use of raw milk from only Grade A listed sources,

product labeling, etc., **are monitored by our plant** at least as well under the NCIMS HACCP alternative as under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

11). "Other" NCIMS requirements, such as, Appendix N drug monitoring, use of raw milk from only Grade A listed sources, product labeling, etc., **are evaluated by the State and the FDA** at least as well under the NCIMS HACCP alternative as under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

12). Under the NCIMS HACCP pilot, the ability to implement corrective actions improved resulting from better training and a deeper understanding of product safety issues based on root cause analysis and internal verification programs.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

13). The HACCP pilot has had no impact on my job responsibilities.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

14). The NCIMS HACCP program has had a positive impact on non-Grade "A" products produced at this plant.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree ( ) NA

15). Buyers reduced their HACCP requirements or auditing frequency since we became listed under the NCIMS HACCP pilot program.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

16). The relationship with my state regulators improved over the course of the HACCP pilot.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

17). The relationship with my FDA Regional Milk Specialist improved over the course of the HACCP pilot.

( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

18). The use of a paid consultant was helpful in development and implementation of the NCIMS HACCP program.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree ( ) NA

19). The NCIMS Technical Assistance Team was a valuable resource.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree ( ) NA

20). I think volunteering for the HACCP pilot was the right decision for my plant.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

E. Summarize the approximate time investment by plant personnel in the HACCP pilot to date:

Training (include trainer & trainee):		HACCP Document Preparation:	_____hours
HACCP Team	_____ hours	Baseline Survey	_____hours
Production Personnel	_____ hours	Advisory Visit(s) by State & FDA	_____hours
45 Day Audit(Prep. & Audit)	_____hours	State Listing Audit(s)	_____hours
4 Month Audit (Prep. & Audit)	_____hours	FDA Check Audit (Prep. & Audit)	_____hours
Verification Activities	_____hours	Validation Activities	_____hours

State Program Evaluation by FDA ____hours HACCP Written Program Review & Updating __hours
Other (Identify)HACCP Operation _____hours
Other (Identify)Correcting deficiencies identified during the various steps of the program _____hours

F.
1. Did the Hazard Analysis change since you were listed? Yes _____ No ____

2. What was the approximate extra cost beyond normal operational expenses under the traditional PMO program for participating in the HACCP pilot? $_____

3. List any hazards evaluated during the hazard analysis that may not have been addressed under your traditional PMO safety program. _____

4. How would you improve the HACCP pilot program (on back)?

Attachment 3. State regulatory Program
Director's Questionnaire

STATE PROGRAM DIRECTOR'S QUESTIONNAIRE

In order for the NCIMS HACCP Pilot Committee Evaluation Team to fully evaluate the pilot we ask that you answer the following questions. We intend to minimize the on-site evaluations so we do not unduly interfere with the operations or inappropriately influence the study. Because we will depend heavily on reports, documents and questionnaires, we would appreciate your prompt response. Please complete this questionnaire using MS WORD then save it with a different name and e-mail it as an attachment to
rgraham@dhhmail.dhh.state.la.us.

Name_____ State_____

Part I

Listed below are a series of statements with which you might agree or disagree. Beneath each statement are five possible responses to each of these statements. Based on your experiences during the NCIMS HACCP Pilot, please mark the response that most closely reflects your opinion regarding each statement.

Note: During the onsite visits by the evaluation team, you will have an opportunity to provide your reasons for, and comments about the responses you provide.

1). State Regulatory audits, state listing audits and FDA audits performed on Pilot Plant(s) in your state provide at least as much verification and assurance of Grade A products as did the inspections, ratings and check ratings under the traditional system.

( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

2). If the NCIMS HACCP pilot is accepted and implemented as an alternative to the current system, the State Listing Officer should be prohibited from having direct regulatory responsibility for a HACCP listed milk plant in which they will perform the listing audit.

( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

3). The current State NCIMS HACCP plant listing(s) provides at least as much verification and assurance of the ongoing safety of Grade A milk products (for each plant that has been listed that I audit) as State Ratings made under the

traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

4). **We are able to evaluate** the "other" NCIMS requirements, such as, Appendix N drug monitoring, use of raw milk from only Grade A listed sources, product labeling, etc., at least as well under the NCIMS HACCP alternative as under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

Part II
Please complete the following:
1. Recognizing the additional advisory, training and monitoring time involved in the start-up of any new program, the amount of time required to regulate plants under HACCP in the future will be **( ) more ( ) the same ( ) less** than that required under the traditional system.
2. Estimate the amount of time (in hours) spent, thus far, on the following activities involved with the Phase II portion of the Pilot Study (Subsequent to January 28, 2002) (If not applicable indicate "NA")
   a. Baseline Survey _____
   b. Advisory Visits to plant _____
   c. State Listing Audits _____
   d. 4 Month Audits _____
   e. "Follow-up" Audits _____
   f. FDA Audit _____

3. What were your one greatest benefit and your one greatest concern derived from this voluntary alternative system?

4. What would you suggest to improve HACCP as a voluntary alternative to the traditional system?

Attachment 4. State Regulatory Milk Plant
Regulatory Auditor's Questionnaire

State Regulatory Auditor's Questionnaire

(State Person Responsible for Routine Regulatory Oversight)

In order for the NCIMS HACCP Pilot Committee Evaluation Team to fully evaluate the pilot we ask that you answer the following questions. We intend to minimize the on-site evaluations so we do not unduly interfere with the operations or inappropriately influence the study. Because we will depend heavily on reports, documents and questionnaires, we would appreciate your prompt response. Please complete this questionnaire using MS WORD then save it with a different name and e-mail it as an attachment to
rgraham@dhhmail.dhh.state.la.us.

Name_____ State_____

Part I

Listed below are a series of statements with which you might agree or disagree. Beneath each statement are five possible responses to each of these statements. Based on your experiences during the NCIMS HACCP Pilot, please mark the response that most closely reflects your opinion regarding each statement.

Note: During the onsite visits by the evaluation team, you will have an opportunity to provide your reasons for, and comments about the responses you provide.

1). The regulatory audits of the Pilot Plant(s) I performed provided at least as much verification and assurance of the safety of Grade A milk products as did the traditional inspections I have performed on similar milk plants. (Answer this question **ONLY** if you have performed one or more audits of the Pilot Plant.)

( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

2). If the NCIMS HACCP pilot is accepted and implemented as an alternative to the current system, the State Listing Officer should be prohibited from having direct regulatory responsibility for a HACCP listed milk plant in which they will perform the listing audit.

( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

3). Under the NCIMS HACCP Pilot, the milk plant is able to verify and assure the safety of Grade A milk products that they produce at least as well as they could under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

4). The current State NCIMS HACCP plant listing(s) provides at least as much verification and assurance of the ongoing safety of Grade A milk products (for each plant that has been listed that I audit) as State Ratings made under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

5). The latest FDA audit of the State NCIMS HACCP listing for plants I audit have provided at least as much verification and assurance of the ongoing safety of Grade A milk products from those plant(s) as FDA check ratings of State ratings have done under the traditional system (complete this question **ONLY** if one or more FDA audits have been completed).
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

6). **We are able to evaluate** the "other" NCIMS requirements, such as, Appendix N drug monitoring, use of raw milk from only Grade A listed sources, product labeling, etc., at least as well under the NCIMS HACCP alternative as under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

7). "Other" NCIMS requirements, such as, Appendix N drug monitoring, use of raw milk from only Grade A listed sources, product labeling, etc., **are monitored by the milk plant** at least as well under the NCIMS HACCP alternative as under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

8). "Other" NCIMS requirements, such as, Appendix N drug monitoring, use of raw milk from only Grade A listed sources, product labeling, etc., **are evaluated by FDA Milk Specialists and State Listing Officers** at least as well under the NCIMS HACCP alternative as under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

Part II

Please complete the following:

1. Recognizing the additional advisory, training and monitoring time involved in the start-up of any new program, the amount of time required to regulate plants under HACCP in the future will be

( ) more ( ) the same ( ) less

than that required under the traditional system.

2. Estimate the amount of time (in hours) spent, thus far, on the following activities involved with the Phase II portion of the Pilot Study (Subsequent to January 28, 2002) (If not applicable indicate "NA")

a. Baseline Survey _____
b. Advisory Visits to plant _____
c. State Listing Audits _____
d. 4 Month Audits _____
e. "Follow-up" Audits _____
f. FDA Audit _____

3. What were your one greatest benefit and your one greatest concern derived from this voluntary alternative system?

4. What would you suggest to improve HACCP as a voluntary alternative to the traditional system?

Attachment 5. State Listing
Officer's Questionnaire

STATE LISTING OFFICER'S QUESTIONNAIRE
(State Person Responsible for NCIMS Ratings and HACCP Listings)

In order for the NCIMS HACCP Pilot Committee Evaluation Team to fully evaluate the pilot we ask that you answer the following questions. We intend to minimize the on-site evaluations so we do not unduly interfere with the operations or inappropriately influence the study. Because we will depend heavily on reports, documents and questionnaires, we would appreciate your prompt response . Please complete this questionnaire using MS WORD then save it with a different name and e-mail it as an attachment to rgrahm@dhhmail.dhh.state.la.us.

Name_____ State_____

Part I

Listed below are a series of statements with which you might agree or disagree. Beneath each question are five possible responses to each of these statements. Based on your experiences during the NCIMS HACCP Pilot, please mark the response that most closely reflects your opinion regarding each statement.
Note: During the onsite visits by the evaluation team, you will have an opportunity to provide your reasons for, and comments about the responses you provide.

1). The Listing audit of the Pilot Plant(s) I performed provided at least as much verification and assurance of the safety of Grade A milk products as did the traditional Sanitation Ratings I have performed on similar milk plants. (Answer this question **ONLY** if you have performed one or more audits of the Pilot Plant.)
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

2). If the NCIMS HACCP pilot is accepted and implemented as an alternative to the current system, the State Listing Officer should be prohibited from having direct regulatory responsibility for a HACCP listed milk plant in which they will perform the listing audit.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

3). Under the NCIMS HACCP Pilot, the milk plant can verify and assure the safety of Grade A milk products that they produce at least as well as they could under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

4). Under the NCIMS HACCP Pilot, the Regulatory agency is able to verify and assure the safety of Grade A milk products from a milk plant at least as well as they could under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

5). The latest FDA audit of the State NCIMS HACCP Pilot listing(s) for plant(s) I have audited provides at least as much verification and assurance of the ongoing safety of Grade A milk products from those plants as FDA check ratings of State ratings I have done under the traditional system (complete this question **ONLY** if one or more FDA audits have been completed).
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

6). "Other" NCIMS requirements, such as, Appendix N drug monitoring, use of raw milk from only Grade A listed sources, product labeling etc., are **evaluated by the State regulatory agency** as well under the NCIMS HACCP pilot alternative as under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

7). "Other" NCIMS requirements, such as Appendix N drug monitoring, use of raw milk from only Grade A listed sources, product labeling, etc., **are monitored by the milk plant** at least as well under the NCIMS HACCP alternative as under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

8). "Other" NCIMS requirements such as Appendix N. drug monitoring, use of raw milk from only Grade A listed sources, product labeling etc., **are evaluated by FDA** at least as well under the NCIMS HACCP alternative as under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

Part II

Please complete the following:

1. Recognizing the additional advisory, training and monitoring time involved in the start-up of any new program, the amount of time required to regulate plants under HACCP in the future will be **( ) more ( ) the same ( ) less** than that required under the traditional system.

2. Estimate the amount of time (in hours) spent, thus far, on the following activities involved with the Phase II portion of the Pilot Study (Subsequent to January 28, 2002) (If not applicable indicate "NA")

   a. Baseline Survey _____
   b. Advisory Visits to plant _____
   c. State Listing Audits _____
   d. FDA Audit _____

3. What were your one greatest benefit and your one greatest concern derived from this voluntary alternative system?

4. What would you suggest to improve HACCP as a voluntary alternative to the traditional system?

Attachment 6. Regional Milk Specialist Questionnaire

Regional Milk Specialist NCIMS HACCP Pilot Questionnaire

In order for the NCIMS HACCP Pilot Committee Evaluation Team to fully evaluate the pilot we ask that you answer the following questions. We intend to minimize the on-site evaluations so we do not unduly interfere with the operations or inappropriately influence the study. Because we will depend heavily on reports, documents and questionnaires, we would appreciate your prompt response. Please complete this questionnaire using MS WORD then save it with a different name and e-mail it as an attachment to rarbaugh@ora.fda.gov

Name_____Region_____

PART I

Listed below are a series of statements that you may either agree or disagree with. Beneath each question are five possible responses to each of these statements. Based on your experiences during Phase II of the NCIMS HACCP Pilot, please mark the response that most closely reflects your opinion regarding each statement.

Note: During the onsite visits by the evaluation team, you will have an opportunity to provide your reasons for, and comments about the responses you provide.

1. FDA audit(s) of the State NCIMS HACCP Pilot listing for plant(s) that I have performed provide at least as much verification and assurance of the ongoing safety of Grade A milk products from the milk plant being audited as FDA check ratings I have performed of similar milk plants under the traditional system. (complete this question **ONLY** if you have performed one or more FDA audits of NCIMS HACCP listings during Phase I or II of the pilot.

( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

2. Under the NCIMS HACCP Pilot, the milk plant can verify and assure the safety of Grade A milk products that they produce at least as well as they could under the traditional system.

( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

3. Under the NCIMS HACCP Pilot, the Regulatory Agency is able to verify and assure the safety of Grade A milk products from a milk plant at least as well as they could under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

4. The current State NCIMS HACCP Pilot listing provides at least as much verification and assurance of the ongoing safety of Grade A milk products from the plant(s) listed as State Ratings made under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

5. "Other" NCIMS requirements, such as, Appendix N drug monitoring, use of raw milk from only Grade A listed sources, product labeling, etc., **are evaluated by the State regulatory agency** at least as well under the NCIMS HACCP alternative as under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

6. "Other" NCIMS requirements, such as, Appendix N drug monitoring, use of raw milk from only Grade A listed sources, product labeling, etc., **are monitored by the milk plant** at least as well under the NCIMS HACCP alternative as under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

7. "Other" NCIMS requirements, such as, Appendix N drug monitoring, use of raw milk from only Grade A listed sources, product labeling, etc., **are evaluated by the State HACCP Listing Officer** at least as well under the NCIMS HACCP alternative as under the traditional system.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

8. The training you received January 2002, in Baltimore, was adequate to prepare you for your responsibilities under the HACCP Pilot Study.
( ) Strongly disagree ( ) Disagree ( ) No opinion ( ) Agree ( ) Strongly agree

PART II
Please complete the following:

1. Estimate the amount of time (in hours) spent on the following activities:
   (NA = Not applicable)
   a. Baseline Survey ____
   b. Advisory Visit(s) to milk plant ____
   c. State Listing Audit ____
   d. 4 Month Audits ____
   e. FDA Audit ____
   f. State Program Evaluation ____

2. What were your one greatest benefit and your one greatest concern derived from this voluntary alternative system?

3. What would you suggest to improve HACCP as a voluntary alternative to the traditional system?

Appendix II.
Listening Session Summary and Response

NCIMS Dairy HACCP Regulatory Agency Listening Session
Discussion of Issues Raised
Southeast Regional Seminar - October 7, 2002

The comments of the regulatory agencies ranged from specific suggestions to more general, occasionally harder to define, concerns.

General Recommendations

1. Be sure that the proposal documents are complete and made available as early as possible. For sure with the conference proposal so that they are all distributed with the proposals.

   The committee agreed. NCIMS Proposal 316 includes these documents.

2. "Hands on training" in a HACCP milk plant preferably in small groups is critical to the uniformity of State and FDA auditors.

   The Committee agreed. A recommended certification document was included with the proposal that specifies small group training as a part of the standardization process.

3. Be sure regulators, listing officers and FDA auditors are well trained (the USDA Meat program was cited as an example of how not to do things).

   The committee has not used the USDA program as a model. The NCIMS HACCP Training committee will provide periodic and ongoing training and training opportunities if the conference delegates accept the proposal.

4. Provide negative as well as positive findings and objective analysis of our findings (there was concern raised about the initial public reports from the Evaluation Team that listed mostly positive findings and then the lack of a more complete public Evaluation Team Report at the 2001 NCIMS).

   The committee agreed and the final NCIMS HACCP Committee Evaluation Team Report is a comprehensive document that includes recommendations as well as raw unedited information from state regulators, FDA Regional Milk Specialists and industry participants so the reader can reach their own conclusions.

5. Our seminar materials (NCIMS HACCP Symposium) should include Phase II and, where it is reasonable to do so, Phase I data summaries and observations. It is in this seminar

data that I believe that we can, and should, respond to concerns identified in this document that we do not address in the proposal.

The committee agreed. The Evaluation Team's report will be available for review at the 2003 NCIMS Conference and much of the raw data has been divided into participants that were included in the Phase I & II pilot and those included only in the Phase II pilot.

6. If some questions remain unanswered, be honest and say so.

The Committee agrees and has followed that guidance. The opportunity to pilot the NCIMS HACCP program for four years and the extensive data gathering conducted by the Committee and Evaluation Team has reduced the number of questions that are unanswered so there is significant certainty regarding the implementation and operation of a voluntary alternative HACCP program within the NCIMS program.

7. Be sure State Dairy Program Directors know what they are getting into.

The Committee agreed and has modified the documents to make very clear the need for upper level regulatory commitment before a State elects to participate in this process.

Concerns and Recommendations Specific to the Pilot

1. Six-month audit frequencies were of concern. The issue was that States were feeling pressure to move to the six month audits when the State preferred to make audits more frequently.

The Committee agreed and has modified the HACCP proposal documents to clearly have the transition from a four month audit frequency to a six month audit frequency remain a decision of the state regulatory agency based on performance criteria applicable to the plant. (see Proposal 316, PMO Appendix K document.).

2. We need specific guidelines for repeat violations observed at regulatory inspections.

The Committee agreed and has modified the documents to make it clear that repeat violations under this HACCP system will be handled in the same manner as under the PMO, using the same authority and regulatory actions as under the current system.

3. Do not lose the construction and general sanitation aspects. (Regulatory personnel in both seafood and poultry HACCP programs stress the importance of not forgetting the sanitation aspects).

The Committee agreed and has modified the HACCP proposal documents to insure that dairy plant facility maintenance and cleanliness is a necessary part of any NCIMS HACCP program.

4. The current document does not make it easy for regulators to keep up with a milk plant that changes a lot. The Florida milk plant made 60 changes in 4 months. It took the regulator several days just to determine what had changed.

The Committee agreed and has modified the documents to require a centralized document control log. The HACCP pilot and the current proposal (316) to the 2003 Conference both require that the plant keep its HACCP written program documents up-to-date with the date of any changes recorded.

5. Do something to minimize the "nightmare" of cross-referencing changes from one product, prerequisite program, hazard analysis or monitoring record to all the others.

The committee agreed and the proposal (316) was modified to require better organization of the HACCP document to facilitate review by regulators.

6. The paperwork is unbelievable. This is made worse because records are not being maintained like they should. Still need to do a physical plant inspection. Find more during the physical inspection than what is found in the audit.

It is true that HACCP requires some additional paperwork from participating plants that has to be review by regulators during audits. However, the proposal was strengthened by including additional document controls. Also, the HACCP pilot training required the auditor to conduct a physical examination of the plant facilities to determine the effectiveness of the plant's HACCP program See questions #5.

7. Maintain the "three tiered" system (the routine regulator is not the listing officer).

The HACCP Committee, after piloting both a two tiered system and a three tiers system has decided to support a three tiered regulatory system and the current proposal (316) to the NCIMS Conference reflects support for the three tier system.

8. Provide more guidance as to what a failure is (a scoring system or other objective criteria) for regulatory, listing and FDA Check Auditing. The line between success and failure in HACCP pilot operations needs to be clarified.

The final proposal has been modified to include critical listing elements (CLEs) that provide more substance to define a HACCP system failure in a dairy plant.

9. Regulators are unsure of what to write on audit report. The plant complains if they write a lot.

It is clear to the HACCP Committee that additional training, as well as standardization of state regulators will be necessary to effectively regulate under a voluntary NCIMS HACCP program.

10. More technical guidance is needed in order to achieve uniformity. (How do you evaluate a plant under HACCP to assure consistency between the states)? The proposed Hazard guide and similar informational materials as well as national standardization of HACCP Listing Officers were seen as needed additions.

The Committee agreed and has included with the proposal, standardization recommendations aimed at achieving uniformity between states that participate in a voluntary NCIMS HACCP program. The Committee also recommends that the HACCP Committee's Technical Resource team be continued if the proposal is accepted to provide national interpretive guidance for the NCIMS HACCP program.

Unsolicited Positive Comment

1. "The good thing of the HACCP program is that plants may accept and justify specific PMO applicable references."

General Concerns
(No suggestions for correction were identified during the listening session)

1. There is seen to be a lack of respect for current system and what it accomplishes (training lecturers and informal comments by HACCP Committee members were cited. Probing for more detail resulted in replays of conversations where individual HACCP Committee members were strongly defending the pilot).

The NCIMS HACCP Committee has always recognized that any voluntary HACCP alternative program will have to be built around the PMO as an excellent source of guidance. A number of the parts of the HACCP proposal are taken directly from the PMO. The HACCP Committee recognized that in order to implement an effective NCIMS HACCP program, it would have to go beyond the PMO and change the emphasis toward a more flexible food safety system.

Several other comments were variations on this theme. They include:

a. What is wrong with the current system?

The current system has proven to be a very effective food safety system to insure consumers are receiving safe and high quality dairy products. The voluntary HACCP alternative program to the current system has been developed to incorporate a different approach to achieving the same goal. This different approach does not replace the current system but adds an option for those plants and states that are interested in operating and regulating dairy plants under HACCP,

a system that is recognized both domestically and internationally for many food products. This is another tool the states and industry have available for assuring the safety of milk and milk products.

b. There is a perception that HACCP is considered better even though it is not yet fully implemented and has not yet been proven (unspoken but clear anyway, this is seen as arrogant and, if the system turns out to be not as good, possibly dangerous).

The committee's charge was to develop and evaluate an alternative HACCP System under the NCIMS program that is at least equivalent to the current PMO-based system. WE believe we have done so. Our charge from the NCIMS delegates was not to evaluate whether HACCP was better than the traditional NCIMS system.

c. It is the traditional regulatory system that makes an industry HACCP system failsafe.

The traditional NCIMS system based on the PMO certainly has a very admirable record of producing safe dairy products. The NCIMS HACCP Committee has developed, from the Phase I and Phase II pilots, a HACCP regulatory system that achieves the same level of dairy product safety as the traditional system. This stand-alone feature of a voluntary NCIMS HACCP program is mandatory for it to be effective in the long run. See the NCIMS HACCP proposal (316), to identify the details of how the HACCP alternative achieves this, specifically the changes from the Phase I and II documents.

d. State officials can't see that a HACCP plant is any better than a plant regulated under the traditional system.

The NCIMS HACCP Committee built a regulatory HACCP system designed to be an equally effective alternative to the traditional system. It was not the Committee's focus to evaluate if HACCP was better than the traditional system. State official s who have participated in the HACCP pilot have found the HACCP System to be equivalent alternative to the traditional system, providing them with more information and a better understanding of plant operations.

e. Before you adopt HACCP be sure that it works as well as the traditional system. Once it's in place you will never get rid of it.

The purpose of piloting an NCIMS regulatory HACCP program has been to provide enough time to evaluate whether it works as well as the traditional system. The Evaluation Team report contains large amount of data that allow the reader to determine whether the NCIMS HACCP Committee has achieved this goal. The NCIMS HACCP Committee believes that proposal 316 is equivalent to the traditional system.

2. HACCP gives States an uneasy feeling**.**

The NCIMS HACCP Committee recognizes that the addition of a voluntary HACCP alternative to the traditional program may be challenging. The NCIMS HACCP Committee has spent four years in an effort to be sure a voluntary alternative to the traditional NCIMS program can achieve the same high standards as established by the traditional PMO-based program. See the Evaluation Team report, particularly the summary of questionnaires from participating states for insight into their experiences under a regulatory HACCP program.

3. States fear pressure from industry if a plant in their State wants to go HACCP even though the States do not have the resources to support that effort. States believe that the HACCP alternative will cost more time and money to get people trained and to get plants up and going and may well use more time long term in a time of rapidly disappearing State budgets. If no additional resources are provided, the drain to the voluntary HACCP alternative could negatively affect other programs they are responsible for. Even if States see the HACCP alternative as equivalent, this is an issue that will need to be addressed to gain their support.

The decision to participate in the voluntary HACCP alternative is completely up to the State (proposal 316) and the industry. Both parties must agree, otherwise the traditional system will be utilized to regulate Grade A dairy plants. This is clearly stated in the proposal.

4. At least one State felt, and did not like feeling, pressure to accept a HACCP pilot plant in their State. (Probing resulted in references to members of HACCP committee encouraging State participation in the pilot).

See the previous answer.

5. Several States expressed views that HACCP is a great QC program but makes poor regulatory program. They cited the Seafood HACCP programs in their southern states that they say are struggling. The consensus of States was that if milk fell to the health levels they see provided under the seafood HACCP program, it could result in a serious loss of public health protection (probing revealed that these folks are either administering or closely observing the seafood HACCP regulatory programs in their own states. This perception is a serious concern among the southern states. I believe that if unaddressed, this lack of confidence in regulatory HACCP will result in at least some serious public health officials in areas of the country with shared milk and seafood programs, such as in the south, opposing the NCIMS dairy HACCP).

The NCIMS HACCP program was developed over a four year period to work out the bugs and problems. The Committee began its efforts to develop an NCIMS HACCP program by researching a number of other regulatory HACCP programs including seafood, meat, and the Canadian dairy HACCP program. It was clear to the Committee that each of these programs had weaknesses that the current NCIMS

HACCP proposal has avoided. The current NCIMS HACCP proposal (316) is not directly comparable to the Seafood HACCP system.

6. There has been a change for the worse in the relationship between the Milk plant and the regulatory since the pilot began. In the south, the relationship between regulators and milk plants has always been considered by the regulators to be a close one. The milk plant normally contacts the regulatory agency a lot as they consider changes. These contacts with regulatory were characterized as being as common as contacts from the plant to their own management. This was generally agreed to by all of the State regulators in the region. The regulatory agencies value and enjoy being in that type of consultative role. In Florida, under the pilot, this relationship abruptly stopped and the relationship between the plant and regulatory has not been what it was (probing for more detail resulted in information that the plant personnel had changed as HACCP was being initiated. The person selected to lead the new plant HACCP program was from a part of the industry where they did not seek out regulatory guidance and where the relationship with regulatory, while cordial was closer to adversarial).

   Further probing of the above concern indicated another, possibly separate concern, that under the pilot the State regulator does not know the milk plant as well as they used to.

The Evaluation Team questionnaire data that was collected from state participants actually showed that relationships between plant and industry personnel generally improved during the pilot. The transition from the traditional NCIMS program to the HACCP pilot system results in a modification in the relationship between the state and plant personnel, demanding a more cooperative approach by both parties to make implementation of the NCIMS HACCP program successful.

7. There is apprehension that the traditional system is being set aside because of some "personal agendas". (Probing for more detail raised no current issues of substance but more of a harkening back to R#5 and some wording in a very old IDFA newsletter that was taken by them to mean that the purpose of HACCP was to better insulate industry from regulatory). Some on the HACCP Committee are perceived to be interested in getting HACCP accepted in order to gain some future consulting business or further some personal end .

The NCIMS HACCP Committee makeup is broad-based to gain input from a wide variety of viewpoints, including state regulators, FDA advisors and industry personnel. The piloting of a HACCP alternative over the last four years has resulted in a very solid foundation without excessive influence by any single group. The NCIMS HACCP Committee meetings were also open to all parties, including non-members as diverse opinions were considered and welcomed.

8. IDFA stopped providing hot lines and news letters to States after they began raising questions, see item above.

The Committee has received the following response from IDFA. "IDFA moved from a "Hot Line" system of distributing information to members and other interested parties to a weekly electronic newsletter and "Alert" system. In order to serve its members and reduce costs, the electronic newsletter and Alerts are distributed only to members. If there is enough interest from state and federal regulators, IDFA would revisit this decision to see whether the distribution of this material could be expanded.

9. There is no score in the IMS List. There should be no way to differentiate (on the IMS List) traditional from HACCP facilities since they are required to be equivalent.

Note, that with the adoption of proposals from the 2001 NCIMS Conference, plant rating scores are no longer published in the IMS List for the traditional system. An enforcement rating score is published for traditional plants, while under the voluntary HACCP alternative, there is no enforcement rating score. However, procedures to obtain correction of poor enforcement practices are including in proposal 316.

10. Some felt that the efforts of the NCIMS HACCP committee, and some of the Committee members, are perceived as being intended to promote HACCP rather that to determine objectively if it is effective.

The committee makeup was broad-based to gain input from diverse viewpoints. Diverse opinions were considered and welcomed. Committee members also had a wide variety of experiences with HACCP. The Evaluation Team was appointed to evaluate all data objectively to determine if the HACCP system was equivalent to the traditional system. See the answer to question #7.

11. How will HACCP equivalency be determined with other countries?

The NCIMS program, whether referring to the traditional PMO-based system or the proposed voluntary HACCP alternative, utilizes established methods to determine equivalency with foreign countries for imported Grade A products. The NCIMS HACCP proposal does not affect or change this equivalency process.

12. Industry requirements for HACCP are promotional.
    a. They see HACCP as a requirement for global trade.
    b. They do not understand the benefits of the traditional system.

While the motivation for industry support of an NCIMS HACCP voluntary alternative is multi-faceted and not universal, it is very clear that the industry understands the traditional NCIMS system. The most prominent industry motivation for an NCIMS HACCP program is to reduce duplication since most dairy product buyers already require plants to have a HACCP system in place.

13. Some plants have expressed the desire to keep things the way they are. They have a plant HACCP program in place and want to continue to run on their terms.

The NCIMS HACCP Committee respected the reluctance of some states and dairy plants to participate in an NCIMS HACCP program so they designed a program that is a full voluntary alternative (proposal 316) to the traditional NCIMS program.

14. Is HACCP going to be required in the future to keep industry competitive?

Yes, the Evaluation Team found that HACCP is currently an industry requirement to do business with many customers.

Appendix III.

Summary of Regulatory Information

(Inspections, HACCP Audits, State Ratings, Pre and Post HACCP Evaluations, FDA Check Ratings, Regulatory Samples)

Comparison of Inspection, Audit and Sample Data from HACCP Pilot Plants

Summary:

In general, items marked on state regulatory inspections, state listings, pre and post-HACCP surveys, state HACCP audits, state HACCP listing audits, and FDA HACCP audits showed good consistency relative to the frequency and types of items debited. State listings and state listing audits generally reflect the conditions noted on state regulatory inspections and state audits.

Comparison of Pre-HACCP and Post-HACCP milk product and water sample results indicate that HACCP Pilot plants performed at least as well under the HACCP system as they did under the traditional system.

The majority of traditional inspections and HACCP audits debited requirements normally managed by prerequisite programs under HACCP. Both the traditional inspection system and HACCP audits concentrated their debits in this area.

Comparison of pre and post-HACCP surveys from HACCP pilot plants that participated in Phase I & II conducted using traditional rating methods and procedures showed:

(1) Three out of four plants (where more complete data was available) improved or performed at the same level when compared to pre-HACCP results.

(2) Items marked on the surveys were less consistent than traditional inspections and listings. This may be true because:

(a) HACCP is a young system being implemented as opposed to the traditional system that has been in place for many years; or

(b) There actually was an increased level of non-compliance with PMO "housekeeping" requirements under HACCP; or

(c) The small sample size for the data may not reflect a true picture of conditions in the HACCP Pilot plants; or

(d) Comparing marks from traditional inspections with audit findings is like comparing oranges and apples, the two are not the same.

Audit findings indicate additional emphasis and training are necessary to ensure previous audit findings are corrected in a timely manner and the hazard analysis and hazard plan are properly prepared and complete.

Based on the comparison of inspection, rating, check rating and sample data from state records before the implementation of the HACCP pilot program with similar data during

the HACCP pilot showed HACCP pilot plant compliance not to be significantly different from the same plant's compliance with the PMO under the traditional system.

Data included in study:

Inspection, listing, check-rating, sampling, auditing, pre-HACCP and post-HACCP survey data from HACCP listed plants was used to prepare this report. Data was requested for each plant two years prior to the plants participation in HACCP through December 31, 2002. No date after December 31, 2002 was included in this analysis. Data from plants that did not achieve HACCP listed status or that were HACCP listed in the final months of 2002 and did not have any sample or audit data after the implementation of the HACCP system in the plant prior to December 31, 2002 were also excluded from the analysis.

Analysis of traditional inspection, listing, and check-rating data from Table I

There were 100 state regulatory inspections, 13 state listings and 11 FDA check-ratings conducted under the traditional system that are included in the data.

1. Comparison of state regulatory inspections, state listings, and FDA check-ratings data:

As expected, the greatest number and variety of violations were marked on state regulatory inspections. Fewer violations were documented on state listings and check-ratings than were marked on state regulatory inspections.

Similarities between items marked:
The following items were marked on between 39% and 64% of all state regulatory inspections respectively:

Items 15aa – Protection from contamination;
2a – Walls and ceilings, smooth, washable, good repair;
9a – Milk plant cleanliness; and
1a – Floors, smooth, impervious.

The following items marked on more than 10% of state regulatory inspections also included 4 out of the 6 most frequently marked items on state listings:

15aa – Protection from contamination
9a – Milk plant cleanliness
1a – Floors, smooth, impervious
5a – Separate rooms

The following items marked on more than 10% of state regulatory inspections also included 3 out of the 6 most frequently marked items on check-ratings:

15aa – Protection from contamination
5a – Separate rooms
10a – Sanitary piping, smooth, impervious

Differences between items marked:

The following items were marked on 15% to 23% of state listings, but less than 10% of the time on state regulatory inspections:

4a – Lighting and ventilation
22a – Surroundings, neat and clean

The following items were marked on 18% to 27% of check-ratings, but less than 10% of the time on state regulatory inspections:

18a – Bottling and packaging performed in a plant where contents pasteurized
19a – Capping and/or closing performed in sanitary manner
18b – Bottling and packaging performed in a sanitary manner

Conclusions:

- In general, there is good consistency between items marked on state regulatory inspections when compared to state listings or to FDA check-ratings.

- State regulatory inspections did not emphasize Item 4a concerning lighting and ventilation or Item 22a concerning surroundings as much as state listings.

- State regulatory inspections did not emphasize Items 18a, 18b, and 19a related to packaging finished dairy products as much as FDA check-ratings.

2. Comparison of state regulatory inspections, state listings, and FDA check-ratings with Pre-HACCP Baseline surveys:

Eight out of ten items marked on Pre-HACCP baseline surveys were included within the items marked more than 10% of the time on state regulatory inspections.

Three out of ten items marked on Pre-HACCP baseline surveys were included within the items marked more than 10% of the time on state listings and FDA check-ratings.

Items 15aa (protection from contamination) and 5a (separate rooms) showed the most consistency and were marked on between 15.4% and 100% of state regulatory inspections, state listings, FDA check-ratings, and Pre-HACCP surveys. Items 9a (milk plant cleanliness) and 10a (sanitary piping) were each marked between 15% and 40% of the time on state regulatory inspections, state listings, and the Pre-HACCP surveys.

Items 7a (water supply) and 16a1a (batch pasteurization) were marked more often on Pre-HACCP surveys than on state regulatory inspections, state listings, or FDA check-ratings.

Conclusions:

Considering the small number of Pre-HACCP surveys included in the data, items marked were generally consistent with debits marked on state regulatory inspections, state listings and FDA check-ratings. All items marked better than one half of the time on Pre-HACCP listings were also among the most debited items marked during state regulatory inspections, listings, and FDA check-ratings.

3. Comparison of state regulatory inspections, state listings, and FDA check-ratings with Post-HACCP Baseline surveys:

Six out of eight items marked on Post-HACCP baseline surveys were included within the items marked more than 10% of the time on state regulatory inspections.

Three out of eight items marked on Post-HACCP baseline surveys were included within the items marked more than 10% of the time on state listings and FDA check-ratings.

Item 15aa (protection from contamination) showed the most consistency and was marked between 38% and 64% of state regulatory inspections, state listings, and FDA check-ratings.

Items 4b (lighting and ventilation) and 13a (storage of cleaned containers and equipment) were marked more often on Post-HACCP surveys than on state regulatory inspections, state listings, or FDA check-ratings.

Conclusions:

In general, items marked on state regulatory inspections, state listings, FDA check-ratings and Post-HACCP surveys showed good consistency relative to the frequency and types of items debited.

4. Comparison of Pre-HACCP and Post-HACCP surveys:

The following five out of ten items marked on Pre-HACCP surveys were also marked on Post-HACCP surveys:

15aa – Protection from contamination;
2a – Walls and ceilings;
9a – Milk plant cleanliness;
11a – Construction and repair of containers and equipment; and
10a – Sanitary piping, smooth and in good repair.

The following five out of Eight items marked on Post-HACCP surveys were also marked on Pre-HACCP surveys:

15aa – Protection from contamination;
2a – Walls and ceilings;
9a – Milk plant cleanliness;
11a – Construction and repair of containers and equipment; and
10a – Sanitary piping, smooth and in good repair.

Fifty percent of items marked on Pre-HACCP and Post-HACCP surveys were identical.

The following items were each marked once on a Pre-HACCP or Post-HACCP survey:

1a – Floors, smooth, good repair;
3a – Door and windows;
4b – Lighting and ventilation;
5a – Separate rooms;
7a – Water supply;
8a – Hand-washing facilities;
13a – Storage of cleaned containers and equipment; and
16a1a – Batch pasteurization.

Conclusions:

In general, items marked on Pre-HACCP and Post-HACCP surveys were consistent and tended to emphasize the same things.

Analysis of HACCP audit data from Table 2

1. Findings related to all three categories of audit data (regulatory, listing and FDA).

   There were 54 state regulatory audits, 17 state listing audits and 8 FDA audits included in the data.

   The following items were marked more often than ten percent of the time for all three audit types (regulatory, listing, and FDA):

   9c – Prerequisite programs and practices monitored;
   9a – Required prerequisite program written;
   9a5 – Protection from adulteration with lubricants;
   10h – Other items as noted;
   5b – Monitoring procedures followed;
   1b – Hazard analysis identifies all food safety hazards;
   10d – Labeling compliance; and
   8a – Required information included in record.

   The next most marked items were:

   7b – Verification activities are conducted;
   9a2 – Condition and cleanliness of food contact surfaces;
   1a – Hazard analysis conducted and written for each type of product;
   6g – Corrective actions documented;
   9d – Prerequisite program monitoring performed;
   10c – Drug residue program records complete;
   8b – Information entered on record at time observed;
   9e – Corrections performed in a timely manner; and
   9g – Prerequisite Program monitoring records adequately reflect conditions.

   Eleven out of the twelve most marked items on state listing audits were also marked in the top twenty most frequently marked items on state regulatory audits.

   Fourteen out of seventeen items marked more than once on FDA audits were also marked in the top twenty most frequently marked items on state regulatory audits.

   Conclusions:

   Based on the high percentage of like marks on state regulatory audits, state listing audits and FDA audits there is good consistency between the different audit types.

2. Comparison of state listing audits with FDA audits:

9 out of 12 or 75% of all debits marked more than 10% of the time on state listing audits were also marked on FDA audits. Audit items marked identically included:

9c– Prerequisite programs and practices monitored;
9a– Required prerequisite program written;
12a – Previous audit findings corrected;
9a5 – Protection of food from adulteration with lubricants;
10h – Other items as noted;
5b – Monitoring procedures followed;
1b – Hazard analysis identifies all potential food safety hazards;
10d – Labeling compliance; and
8a – Required information included in the record.

FDA audits marked the following items 25% of the time when the state listings did not:

1a – Hazard analysis conducted for each kind of product;
10c – Drug residue control program records complete;
8b – Processing information entered on records at time observed; and
1c – Hazard analysis reassessed after changes.

State listing audits marked the following items 10% or more of the time when FDA audits did not:

7b – Verification activities are conducted and comply;
9a2 – Condition and cleanliness of equipment food contact surfaces; and
7e – CCP monitoring records reviewed and document values within limits.

Conclusions:

- Audit items 9c, 9a, 12a, 9a5, 10h, 5b, 1b, 10d, and 8a indicate there is good agreement between state regulatory audits, state listing audits and FDA audits on general compliance with NCIMS HACCP program requirements.

- Differences between items marked on FDA audits as compared to items marked on state listing audits indicate FDA audits placed a greater emphasis on: (i) reviewing each plants hazard analysis and comparing it to the products produced; and (ii) ensuring the hazard analysis is maintained up to date and reviewed after changes or at least annually.

- Differences between items marked on state listing audits as compared to items marked on FDA audits indicate state listing personnel placed a greater emphasis on equipment cleaning, pasteurization records, and verification activities.

- The consistent marking of audit “item 12a – Previous audit findings corrected” is likely to be associated with: (i) the failure of state regulators performing audits to consistently establish timelines for corrections when completing state regulatory audits (especially during phase I of the HACCP Pilot); (ii) the fact that only one state performed followup audits routinely; and (iii) confusion on the part of state regulators and industry participants concerning their roles and proper completion of the audit form.

- The frequent marking of Item 1a -- Hazard analysis conducted and written for each kind or group of milk product; Item 1b -- Hazard analysis identifies all potential food safety hazards; and Item 1c -- Hazard analysis reassessed after changes or at least annually, indicates additional training to emphasis the proper completion and maintenance of the hazard analysis is needed.

TABLE 1
Data from 100 state regulatory inspections, 13 state listings and 11 FDA check-ratings under the traditional system prior to the implementation of HACCP in the Pilot Plants

% marked on state reg. insp.	% marked on state listings	% marked on FDA Check-Ratings	% marked on pre-HACCP Baseline Surveys	% marked on Post-HACCP surveys	Inspection item	Description
64	38.5	45.5	100.0	75.0	15aa	Protection from contamination, Operations conducted and located so as to preclude contamination of milk, milk products, ingredients, containers, equipment, and utensils
44		9.1	25.0	25.0	2a	Walls and Ceilings, Smooth, washable, light-colored, good repair
40	15.4	9.1	25.0	25.0	9a	Milk Plant Cleanliness, Neat, clean, no evidence of insects or rodents, trash properly handled
39	23.1			25.0	1a	Floors, Smooth, impervious, no pools, good repair, trapped drains
25	7.7	9.1	25.0	50.0	11a	Construction and repair of containers and equipment, Smooth, impervious, corrosion-resistant, not-toxic, easily cleanable materials, good repair, accessible for inspection
20		9.1			17a	Cooling of milk, Raw milk maintained at 45 F or less until processed
19		9.1			14a	Storage of single-service articles, Received, stored and handled in a sanitary manner, paperboard containers not reused except as permitted
19	15.4	18.2	50.0		5a	Separate Rooms, separate rooms as required, adequate size
18	7.7		25.0		3a	Doors and Windows, All outer openings effectively protected against entry of flies and rodents
17					12a	Cleaning and sanitizing of containers/equipment, containers, utensils, and equipment effectively cleaned
15		18.2	25.0	50.0	10a	Sanitary Piping, Smooth, impervious, corrosion-resistant, non-toxic, easily cleanable materials, good repair, accessible for inspection
12					12b	Cleaning and Sanitizing of containers and equipment, Mechanical cleaning requirements of Ordinance in Compliance, records complete
11		9.1	25.0		8a	Hand-Washing Facilities, Located and equipped as required, clean and in good repair, improper facilities not used
10	15.4				4a	Lighting and ventilation, adequate in all rooms
8	7.7	27.3			18a	Bottling and Packaging, Performed in a plant where contents finally pasteurized
7				25.0	13a	Storage of cleaned containers and equipment, stored to assure drainage and protected from contamination
6					16eb	Recording Charts, HTST & HTST pasteurizer chards comply with applicable Ordinance requirements
6	7.7	18.2			19a	Capping, Capping and/or closing performed in sanitary manner by approved mechanical equipment
6					16ea	Recording charts, batch pasteurizer charts comply with applicable Ordinance requirements
5					12c	Cleaning and sanitizing of containers and equipment, approved sanitizing process applied prior to use of product contact surfaces
4					17c	Cooling of milk, Approved thermometer properly located in all refrigeration rooms and storage tanks
4	23.1				22a	Surroundings, Neat and clean, free of poled water, harborages and breeding areas
4					20a	Personnel cleanliness, Hands washed clean before performing plant functions, rewashed when contaminated
3		9.1	25.0		7a	Water supply, constructed and operated in accordance with Ordinance
3					21a	Vehicles, Vehicles clean, constructed to protect milk
3		18.2			18b	Bottling and packaging, performed in a sanitary manner by approved mechanical equipment
2					17d	Re-circulated cooling water from safe source and properly protected, complies with bacteriological standards
2					17b	Pasteurized milk and milk products, except those to be cultured, cooled immediately to 45 F or less in approved

TABLE 1
Data from 100 state regulatory inspections, 13 state listings and 11 FDA check-ratings under the traditional system prior to the implementation of HACCP in the Pilot Plants

% marked on state reg. insp.	% marked on state listings	% marked on FDA Check-Ratings	% marked on pre-HACCP Baseline Surveys	% marked on Post-HACCP surveys	Inspection item	Description
						equipment, all milk and milk products stored threat until delivered
2					15bb	Cross connections, overflow, spilled and leaked products or ingredients discarded
2					10c	Sanitary piping, Pasteurized products conducted in sanitary piping , except as permitted by Ordinance
2	7.7				7b	Water supply, No direct or indirect connection between safe and unsafe water
2					6a	Toilet facilities, complies with ordinance
1		9.1			15ab	Protection from contamination, air and steam used to process products in compliance with Ordinance
1					10b	Sanitary piping, Mechanically cleaned lines meet Ordinance specs
1					19b	Capping, Imperfectly capped/closed products properly handled
1		9.1			16da	Regenerative heating, Pasteurized or aseptic product in regenerator automatically under greater pressure than raw product in regenerator at all times
1					16c2a	Aseptic Processing, Flow-diversion device complies with Ordinance requirements
1					15bc	Cross Connections, No direct connections between milk or milk products and cleaning and/or sanitizing solutions
1					11c	Construction and repair of containers and equipment, approved single-service articles, not reused
1					9b	Milk plant cleanliness, no unnecessary equipment
1					6c	Toilet facilities, clean, well-lighted and ventilated, proper facilities
1					5c	Separate rooms, storage tanks properly vented
1				25.0	4b	Lighting and ventilation, well ventilated to preclude odors and condensation, filtered air with pressure systems
1					3b	Doors and windows, outer doors self-closing, screen doors open outward
		9.1			15ac	Approved pesticides, safely used
	7.7				7c	Water supply, Condensing water and vacuum water in compliance with Ordinance requirements.
			25.0		16a1a	Pasteurization Batch: Indicating/recording thermometers comply with ordinance
					16c1a	Aseptic Processing indicating/recording thermometers comply with Ordinance
		9.1			16b2d	Pasteurization, HTST: Flow promoting devices comply with Ordinance requirements

TABLE 1A
State Regulatory Inspections data under the Traditional System

Plant ID	Inspection Date	1a	2a	3a	3b	4a	4b	5a	5c	6a	6c	7a	7b	8a	9a	9b	10a	10b	10c	11a	11c	12a	12b	12c	13a	14a	15aa	15ab	15bb	15bc	16c2a	16da	16ea	16eb	17a	17b	17c	17d	18a	18b	19a	19b	20a	21a	22a
A	11/20/00														x												x							x											
A	2/13/01					x									x												x							x											
A	5/8/01					x									x								x																						
A	8/14/01														x								x				x			x															
B	1/21/98		x																																										
B	4/23/98			x																							x								x										
B	7/30/98		x												x												x								x										
B	10/23/98														x												x								x										
B	1/28/99	x	x												x												x									x									
B	4/29/99																					x				x																			
B	7/30/99														x							x														x								x		
B	10/14//9																										x																		
C	7/20/98																										x										x								
C	10/16/98	x		x											x												x																		
C	1/15/99																					x					x																		
C	4/15/99	x																				x					x																		
C	7/14/99	x																									x																		
C	10/14/99																					x		x			x																		
C	11/1/00	x	x									x			x																															
D	4/12/00		x												x											x																			
D	7/6/00		x	x											x					x							x																		
D	10/3/00	x	x									x								x							x																		
D	1/25/01		x												x												x																		

TABLE 1A
State Regulatory Inspections data under the Traditional System

Plant ID	Inspection Date	1a	2a	3a	3b	4a	4b	5a	5c	6a	6c	7a	7b	8a	9a	9b	10a	10b	10c	11a	11c	12a	12b	12c	13a	14a	15aa	15ab	15bb	15bc	16c2a	16da	16ea	16eb	17a	17b	17c	17d	18a	18b	19a	19b	20a	21a	22a
D	4/17/01	x	x												x	x				x						x	x																	
D	7/17/01	x	x																	x						x	x				x													
E	12/16/98	x																				x					x						x											
E	3/24/99																			x							x							x											
E	6/24/99	x																				x					x							x											
F	1/12/00	x	x			x		x						x	x		x					x		x		x	x								x										
F	4/12/00	x	x	x				x		x				x	x		x								x	x	x													x		x				
F	7/24/00	x	x	x				x		x					x		x			x					x	x	x								x					x					
F	10/26/00	x	x					x				x			x		x			x						x	x								x								x		
F	1/18/01	x	x	x		x		x						x	x		x			x			x			x	x								x					x					
F	4/9/01	x	x	x				x						x	x		x			x			x		x	x	x								x								x		
F	7/11/01	x	x	x				x						x	x		x			x					x	x	x													x					
F	10/29/01	x	x			x		x							x		x									x	x								x										
F	1/3/02	x	x	x	x										x		x			x					x	x	x								x								x		
F	4/26/02	x	x			x		x						x	x		x									x	x								x					x		x			
F	7/23/02	x	x	x		x		x						x	x		x			x						x	x								x					x					x
G	5/26/98																										x																	
G	8/27/98													x																															
G	11/18/98																			x			x																						
G	2/3/99																										a																		
G	3/9/99																			x																									
G	5/6/99																							x			x																	
G	8/23/99														x							x					x																	
G	11/30/99																																											
G	12/13/99																																											
G	2/28/00																										x																	
H	10/9/97																x																					x						
H	1/16/98																																	x										
H	4/6/98																																											
H	7/8/98																																											

TABLE 1A
State Regulatory Inspections data under the Traditional System

Plant ID	Inspection Date	1a	2a	3a	3b	4a	4b	5a	5c	6a	6c	7a	7b	8a	9a	9b	10a	10b	10c	11a	11c	12a	12b	12c	13a	14a	15aa	15ab	15bb	15bc	16c2a	16da	16ea	16eb	17a	17b	17c	17d	18a	18b	19a	19b	20a	21a	22a
H	10/26/98																										x																		
H	1/13/19\																			x																	x								
H	4/27/19																																												
H	8/3/199		x	x													x	x		x	x	x					x		x									x						
H	11/24/19	x	x										X		x		x			x		x				x	x		x								x								
I	1/4/01	x	x					x																			x																		
I	4/5/01	x																	x																											x
I	7/11/01	x																	x																											
I	10/9/01	x									x																																		
J	11/12/97	x	x												x												x								x										
J	2/13/98	x	x					x						x								x		x			x																	
J	5/1/98	x	x	x		x		x															x			x	x						x		x						x			
J	8/14/98	x	x					x																			x						x											
J	11/13/98	x	x	x		x														x			x				x						x		x									
J	2/1/99	x	x					x															x				x								x									
J	5/5/99	x	x	x																		x		x		x	x						x		x									
J	8/12/99	x	x					x												x					x	x							x		x						x			
J	11/16/99	x	x					x							x												x					x									X			
K	1/19/01																x																												
K	2/23/01																																												
K	4/27/01																																				x								
K	6/7/01																																												
K	8/17/01												X																																
K	10/9/01																						x																						
L	4/21/00	x	x												x					x							x																		
L	7/26/00	x		x											x							x	x				x																		
L	10/13/00	x		x			x															x	x												x									
L	1/19/01																					x			x		x																		
L	4/30/01		x																	x							x							x										
L	7/18/01		x												x												x																		

TABLE 1A
State Regulatory Inspections data under the Traditional System

Plant ID	Inspection Date	1a	2a	3a	3b	4a	4b	5a	5c	6a	6c	7a	7b	8a	9a	9b	10a	10b	10c	11a	11c	12a	12b	12c	13a	14a	15aa	15ab	15bb	15bc	16c2a	16da	16ea	16eb	17a	17b	17c	17d	18a	18b	19a	19b	20a	21a	22a
L	10/17/01	x	x																				x				x																	
L	11/30/01														x							x																							
L	12/28/01														x					x							x																	
L	1/4/02		x			x			x						x												x																	
M	2/3/00		x					x																			x											x						x
M	5/4/00														x																		x										x
M	8/15/00													x	x					x																							
M	11/29/00		x												x																												
M	2/8/01																										x																
M	5/4/01																																									x	
M	6/26/01																																							x		x		
M	9/12/01		x	x											x												x															x	
M	12/19/01		x																								x																
M	3/6/02																			x							x	x															
M	6/1/02		x	x										x						x																							
	# Marked	39	44	18	1	10	1	19	1	2	1	3	2	11	40	1	15	1	2	25	1	17	12	5	7	19	64	1	2	1	1	1	6	6	20	2	4	2	8	3	6	1	4	3	4
	% Marked	39.0	44.0	18.0	1.00	10.0	1.00	19.0	1.00	2.00	1.00	3.00	2.00	11.0	40.0	1.00	15.0	1.00	2.00	25.0	1.00	17.0	12.0	5.00	7.00	19.0	64.0	1.00	2.00	1.00	1.00	1.00	6.00	6.00	20.0	2.00	4.00	2.00	8.00	3.00	6.00	1.00	4.00	3.00	4.00

TABLE 1-B
Items Debited on State Listings Under the Traditional System
(Prior to HACCP Pilot Participation)

Plant ID Code	Date of Rating	1a	2a	3a	4a	5a	7a	7b	7c	8a	9a	10a	11a	14a	15aa	15ab	15ac	16b2d	16da	17a	18a	18b	19a	22a
A	8/8/00																							
A	9/20/01					x															x		x	
D	5/2/00																							
D	10/10/01										x		x		x									
D	4/15/02	x									x				x									
E	10/8/01			x																				
F	9/26/00																							
I	4/16/99	x			x			x	x						x									
I	4/12/01	x			x										x									x
K	12/10/98					x																		x
K	11/16/00														x									x
L	11/10/98																							
L	11/1/00																							
	# MARKED	3	0	1	2	2	0	1	1	0	2	0	1	0	5	0	0	0	0	0	1	0	1	3
	% MARKED	23.1	0.0	7.7	15.4	15.4	0.0	7.7	7.7	0.0	15.4	0.0	7.7	0.0	38.5	0.0	0.0	0.0	0.0	0.0	7.7	0.0	7.7	23.1

TABLE 1-C
Items Debited on FDA Check-Ratings Under the Traditional System
(Prior to HACCP Pilot Participation)

Plant ID Code	Date of Check-Rating	1a	2a	3a	4a	5a	7a	7b	7c	8a	9a	10a	11a	14a	15aa	15ab	15ac	16b2d	16da	17a	18a	18b	19a	22a
A	1/28/99																				x		x	
A	6/27/01														x	x								
E	11/8/99																							
F	5/11/99											x								x	x			
H	1/16/00												x		x							x	x	
H	7/17/00																x	x				x		
J	1/3/01		x									x												
K	1/23/96										x				x						x			
K	5/18/99					x				x					x									
L	11/19/97						x												x					
M	6/26/00					x								x	x									
	# MARKED	0	1	0	0	2	1	0	0	1	1	2	1	1	5	1	1	1	1	1	3	2	2	0
	% MARKED	0.00	9.10	0.00	0.00	18.2	9.10	0.00	0.00	9.10	9.10	18.2	9.10	9.10	45.5	9.10	9.10	9.10	9.10	9.10	27.3	18.2	18.2	0.00

TABLE 2

Data from 54 State Regulatory Audits, 17 State HACCP Listing Audits and 8 FDA Check-Audits of HACCP Pilot Plants
Shaded areas represent items marked more than 10% of the time.

% of state Audits marked	%of State listing Audits	% of FDA Audits	Audit form item	Description of item
49.1	17.6	62.5	9c	Prerequisite programs and practices monitored as required
34.5	11.8	75.0	9a	Required Prerequisite program written, implemented and in substantial compliance by firm.
27.3	11.8	37.5	12a	Previous audit findings corrected
21.8	17.6	12.5	9a5	Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate and other chemical, physical and biological contaminants
20			12b	Previous audit findings remain corrected at time of this audit
20	11.8		7b	Verification activities are conducted and comply with HACCP Plan
18.2	35.3		9a2	Condition and cleanliness of equipment food contact surface
16.4	11.8	50.0	10h	Other items as noted
16.4	11.8	25.0	5b	Monitoring procedures as defined in the HACCP plan followed
14.5		25.0	1a	Hazard analysis conducted and written for each kind or group of milk or milk product processed
14.5	5.9	25.0	6g	Corrective actions documented
14.5	5.9	25.0	9d	Prerequisite program monitoring performed at a frequency to ensure conformance
12.7		25.0	10c	Drug residue control program records complete
12.7	11.8	25.0	1b	Hazard analysis identifies all potential food safety hazards and determines those that are reasonable likely to occur(including hazards within and outside the processing plant environment)
10.9	17.6	25.0	10d	Labeling compliance as required
10.9	11.8	25.0	8a	Required information included in the record – e.g. name/location of processor &/or date/time of activity &/or signature/initials of person performing operation &/or identity of product/product code.
10.9		25.0	8b	Processing/other information entered on record at time observed
10.9	5.9		9a3	Prevention of cross contamination from insanitary objects and or practices to food products, packaging material and other food contact surfaces, including utensils, gloves, outer garments, etc, and from raw product to processed product (e.g. pasteurizer pressure differential)
10.9	5.9	25.0	9e	Corrections performed in a timely manner when PP monitoring records reflect deficiencies or non-conformities
10.9		12.5	9g	PP monitoring records adequately reflect conditions observed

TABLE 2

Data from 54 State Regulatory Audits, 17 State HACCP Listing Audits and 8 FDA Check-Audits of HACCP Pilot Plants
Shaded areas represent items marked more than 10% of the time.

% of state Audits marked	%of State listing Audits	% of FDA Audits	Audit form item	Description of item
9.1		25.0	1c	Hazard analysis reassessed after changes in raw materials, formulations, processing methods/systems, distribution, intended use or consumers
9.1	5.9	12.5	5d	Monitoring record data consistent with the actual value(s) observed during the audit
9.1	5.9		7c	Reassessment of HACCP plan conducted annually, or after changes that could affect the hazard analysis or after significant changes in the operation including raw materials and/or source, product formulation, processing methods/systems, distribution intended use or intended consumer.
9.1	5.9		9a8	Pest exclusion from the food plant
9.1		12.5	9f	Prerequisite program audited by firm
7.3	5.9	12.5	11a	Employees trained in monitoring operations
7.3		12.5	6a	Corrective actions when defined in the HACCP plan were followed when deviations occurred
7.3		12.5	6c	Corrective action taken for products produced during a deviation from critical limits defined in the HACCP plan
7.3	5.9		7d	Calibration of CCP process monitoring instruments performed as required and at the frequency defined in the HACCP plan
7.3	11.8		7e	CCP monitoring records reviewed and document that values are within critical limits as required.
7.3			8e	HACCP records correct, complete and available for official review
7.3	5.9	12.5	9a1	Safety of the water that comes into contact with food or food contact surfaces (including steam & ice);
7.3	5.9		9b	Additional PP's required or justified by the hazard analysis are written & implemented by firm
5.5			10e	Prevention of adulteration of milk products
5.5	5.9		11d	Employees trained in prerequisite program operations
5.5			1d	Hazard analysis signed and dated as required
5.5	5.9	25.0	2c	HACCP plan identifies all food safety hazards that are reasonably likely to occur.
5.5			2d	HACCP plan signed and dated as required
5.5	5.9	12.5	5a	HACCP plan defines monitoring procedures for each critical control point. (what, how, frequency, whom
5.5		12.5	6d	Affected product produced during the deviation segregated and held, AND a review to determine product acceptability performed, AND Corrective action taken to ensure that no adulterated and/or product that is injurious to health enters commerce
5.5	5.9		7a	HACCP plan defines verification procedures, including frequency
5.5			7f	Corrective action record reviewed as required

TABLE 2

Data from 54 State Regulatory Audits, 17 State HACCP Listing Audits and 8 FDA Check-Audits of HACCP Pilot Plants
Shaded areas represent items marked more than 10% of the time.

% of state Audits marked	%of State listing Audits	% of FDA Audits	Audit form item	Description of item
5.5		12.5	7h	Records reviewed as required – including date and signature
5.5	5.9		9a4	Maintenance of hand washing, hand sanitizing, & toilet facilities
5.5	5.9	12.5	9h	Prerequisite program signed and dated as required
3.6		12.5	10a	Raw milk supply from NCIMS listed source(s)
3.6			10f	Regulatory samples comply with standards
3.6		25.0	2a	HACCP plan prepared for each kind or group of milk or milk product processed
3.6	5.9		4a	HACCP plan lists critical limits for each CCP
3.6		12.5	4b	Critical Limit(s) are adequate to control the hazard identified
3.6		12.5	4d	Critical Limit(s) are met
3.6	5.9		5c	Monitoring procedures as defined in the HACCP plan adequately measure critical limits at each critical control point.
3.6		12.5	6e	Cause of deviation was corrected
3.6			7g	Calibration records and end product or in process testing results defined in HACCP Plan reviewed as required
3.6			8c	Records retained as required - e.g. one year for refrigerated products/ two years for preserved, shelf-stable or frozen products
1.8		12.5	11b	HACCP plan reassessment performed by trained individual
1.8		12.5	12c	State Enforcement Audit Reports issued and follow- up conducted as required (HACCP Listing Audits & FDA Audits only).
1.8			12d	A series of observations that lead to a finding of a potential HACCP System failure that is likely to result in a compromise to food safety.
1.8		12.5	6b	Predetermined corrective actions defined in the HACCP plan ensure the cause of the deviation is corrected

TABLE 2-A
State Regulatory Audit HACCP Data

Plant	Audit Date	1a	1b	1c	1d	2a	2c	2d	4a	4b	4d	5a	5b	5c	5d	6a	6b	6c	6d	6e	6g	7a	7b	7c	7d	7e	7f	7g	7h	8a	8b	8c	8e	9a	9a1	9a2	9a3	9a4	9a5	9a8	9b	9c	9d	9e	9f	9g	9h	10a	10c	10d	10e	10f	10h	11a	11b	11d	12a	12b	12c	12d
A	12/16/02																						x													x			x						x																
A	10/30/02																																		x	x			x		x					x																
B	8/21/02																																			x																												
B	2/21/02																																			x	x																												
B	8/23/01																																									x																								
B	2/22/01																																									x																								
B	6/27/00																																	x																														
B	6/22/00																																	x									x	x																						
B	2/29/00																																									x																								
C	7/26/01																																									x																								
C	1/31/01																																	x																														
C	9/20/00																																									x																								
C	8/31/00																																																															x			
C	6/30/00	x																																									x																								
C	3/30/00																																																																
D	11/26/02						x																x						x																																				
E	7/18/01																						x								x																																		
E	5/25/01																								x						x																																		
E	4/30/01																																																																x			
E	1/31/01																																																																	
E	11/27/00		x										x			x				x	x																																														
E	9/11/00																						x		x	x	x																																								
E	5/31/00													x							x	x													x																																
F	10/29/02																																			x	x	x	x			x																								
G	8/29/02	x	x										x										x			x		x		x				x	x		x		x																										
G	4/18/02		x																		x		x	x									x		x				x																										
G	12/13/01												x		x									x																																											
G	7/12/01												x		x																		x	x																																
G	3/23/01																																	x																														
G	11/30/00																																	x																														
G	7/12/00									x		x					x											x	x	x																																		
G	4/24/00				x							x		x	x			x			x		x			x								x																														
H	12/14/02			x																	x												x			x			x	x	x			x		x													x		

TABLE 2-A
State Regulatory Audit HACCP Data

Plant	Audit Date	1a	1b	1c	1d	2a	2c	2d	4a	4b	4d	5a	5b	5c	5d	6a	6b	6c	6d	6e	6g	7a	7b	7c	7d	7e	7f	7g	7h	8a	8b	8c	8e	9a	9a1	9a2	9a3	9a4	9a5	9a8	9b	9c	9d	9e	9f	9g	9h	10a	10c	10d	10e	10f	10h	11a	11b	11d	12a	12b	12c	12d
H	12/12/02			x																	x											x																												x			
H	5/8/02			x								x																			x																													x			
H	12/19/01	x																													x																												x	x			
H	9/24/01	x			x			x													x		x	x						x																												x	x			
H	4/18/01																						x	x																																					x	x			
H	11/30/00																	x																																												x	x			
H	8/4/00	x	x	x		x			x			x	x			x			x						x					x	x			x																											x			
H	7/17/00	x	x							x								x				x											x																											x	x			
H	4/20/00	x																x															x																															
I	11/25/02																																																																			
I	7/23/02							x																			x																																						
J	7/29/02												x																							x	x		x	x						x														x			
J	8/9/01																																									x																				x			
J	2/5/01																						x											x								x																		x			
J	10/2/00																																	x								x																				x			
J	5/30/00						x																											x								x																							
J	3/20/00														x																																																		x			
K	12/6/02		x																																																																	
L	12/11/02																																			x			x																												
L	8/8/02																													x																																				
M	10/7/02																																		x		x	x	x	x		x																							
	# Marked	8	7	5	3	2	3	3	2	2	2	3	9	2	5	4	1	4	3	2	8	3	11	5	4	4	3	2	3	6	6	2	4	19	4	10	6	3	12	5	4	27	8	6	5	6	3	2	7	6	3	2	9	4	1	3	15	11	1	1
	% Marked	14.5	12.7	9.10	5.50	3.60	5.50	5.50	3.60	3.60	3.60	5.50	16.4	3.60	9.10	7.30	1.80	7.30	5.50	3.60	14.5	5.50	20.0	9.10	7.30	7.30	5.50	3.60	5.50	10.9	10.9	3.60	7.30	34.5	7.30	18.2	10.9	5.50	21.8	9.10	7.30	49.1	14.5	10.9	9.10	10.9	5.50	3.60	12.7	10.9	5.50	3.60	16.4	7.30	1.80	5.50	27.3	20.0	1.80	1.80

TABLE 2-B
HACCP Audit Data for FDA Check-Audits of State HACCP Listings

Plant Code	Audit ate	1a	1b	1c	2a	2c	4a	4b	4d	5a	5b	5c	5d	6a	6b	6c	6d	6e	6g	7a	7b	7c	7e	7h	8a	8b	9a	9a1	9a2	9a3	9a4	9a5	9a8	9b	9c	9d	9e	9f	9g	9h	10a	10c	10d	10h	11a	11b	11d	12a	12c
B	6/2/00																										x															x							
C	8/2/00	x			x																						x								x		x				x			x				
E	8/28/00		x			x					x			x					x					x			x								x	x	x	x	x	x		x					x	
G	9/19/00								x							x	x										x								x										x	x				
H	8/9/02			x																						x		x				x				x									x					
H	7/17/00	x	x	x	x			x		x	x		x		x			x	x						x	x	x								x							x	x	x		x		x	x
J	5/30/00					x																			x		x								x														x	
K	12/5/02																																																	
# Marked		2	2	2	2	2	0	1	1	1	2	0	1	1	1	1	1	1	2	0	0	0	0	1	2	2	6	1	0	0	0	1	0	0	5	2	2	1	1	1	1	2	2	4	1	1	0	3	1
% Marked		25.0	25.0	25.0	25.0	25.0	00.0	12.5	12.5	12.5	25.0	00.0	12.5	12.5	12.5	12.5	12.5	12.5	25.0	00.0	00.0	00.0	00.0	12.5	25.0	25.0	75.0	12.5	00.0	00.0	00.o	12.5	00.0	00.0	62.5	25.0	25.0	12.5	12.5	12.5	12.5	25.0	25.0	50.0	12.5	12.5	00.0	37.5	12.5

TABLE 2-C
HACCP Audit Data for State HACCP Listings

Plant ID Code	Audit Date	1a	1b	1c	2a	2c	4a	4b	4d	5a	5b	5c	5d	6a	6b	6c	6d	6e	6g	7a	7b	7c	7e	7h	8a	8b	9a	9a1	9a2	9a3	9a4	9a5	9a8	9b	9c	9d	9e	9f	9g	9h	10a	10c	10d	10h	11a	11b	11d	12a	2
A	11/22/02																												x																				
A	11/21/02		x																										x																				
B	2/9/00																																																
C	1/29/02																																															
C	2/24/00																																		x									x					
D	9/6/02					x																	x																						x				
E	4/10/00						x					x							x	x															x															
F	9/12/02																				x			x					x	x		x	x	x									x						
G	12/18/01										x		x									x															x	x									x			
G	3/14/00																										x																						
H	2/19/02										x																	x	x			x																
H	2/24/00									x															x																	x							
I	6/4/02																												x																			
J	1/28/02																										x		x		x	x													x			x	
J	2/3/00																				x														x										x				x	
K	6/27/00																																																
L	7/1/02																							x	x																									
# Marked		**0**	**2**	**0**	**0**	**1**	**1**	**0**	**0**	**1**	**2**	**1**	**1**	**0**	**0**	**0**	**0**	**0**	**1**	**1**	**2**	**1**	**1**	**2**	**2**	**0**	**2**	**1**	**6**	**1**	**1**	**3**	**1**	**1**	**3**	**1**	**1**	**0**	**0**	**1**	**0**	**0**	**3**	**2**	**1**	**0**	**1**	**2**	**0**
% Marked		**00.0**	**11.8**	**00.0**	**00.0**	**5.90**	**5.90**	**0.00**	**0.00**	**5.90**	**11.8**	**5.90**	**5.90**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**5.90**	**5.90**	**11.8**	**5.90**	**5.90**	**11.8**	**11.8**	**0.00**	**11.8**	**5.90**	**35.3**	**5.90**	**5.90**	**17.6**	**5.90**	**5.90**	**17.6**	**5.90**	**5.90**	**0.00**	**0.00**	**5.90**	**0.00**	**0.00**	**17.6**	**11.8**	**5.90**	**0.00**	**5.90**	**11.8**	**0.00**

*TABLE 3**
PRE HACCP MILK PRODUCT AND WATER SAMPLE RESULTS

Pre HACCP Listing

Plant Id Code	# Milk Product Samples	# Violative SPC	% Violative SPC	# Violative Coliform	% Violative Coliform	# Water Samples	# Violative Water Results	% Violative Water Results
A	215	1	0.47	0	0.00	13	0	0.00
B	124	0	0.00	0	0.00	0	0	0.00
C	68	1	1.47	1	1.47	10	1	10.00
D	155	0	0.00	0	0.00	15	0	0.00
E	191	5	2.62	3	1.57	46	8	17.39
F	403	5	1.24	1	0.25	48	13	27.08
G	316	1	0.32	3	0.95	47	3	6.38
H	457	1	0.22	0	0.00	10	1	10.00
I	130	1	0.77	0	0.00	0	0	0.00
J	101	1	0.99	0	0.00	10	2	20.00
K	34	0	0.00	0	0.00	4	0	0.00
L	347	2	0.58	8	2.31	25	0	0.00
M	393	4	1.02	0	0.00	4	0	0.00
Summary	2934	22	0.75%	16	0.55%	232	28	12.07%

TABLE 4
POST HACCP MILK PRODUCT AND WATER SAMPLE RESULTS

Post HACCP Listing

PLANT ID CODE	# Milk Product Samples	# Violative SPC	% Violative SPC	# Violative Coliform	% Violative Coliform	# Water Samples	# Violative Water Results	% Violative Water Results
A	8	0	0.00	0	0.00	1	0	0.00
B	283	3	1.06	0	0.00	5	0	0.00
C	118	2	1.69	0	0.00	55	2	3.64
D	18	0	0.00	0	0.00	0	0	0.00
E	104	2	1.92	3	2.88	24	5	20.83
F	48	4	8.33	0	0.00	0	0	0.00
G	436	4	0.92	3	0.69	50	2	4.00
H	441	0	0.00	5	1.13	10	0	0.00
I	38	0	0.00	0	0.00	7	1	14.29
J	168	2	1.19	1	0.60	8	1	12.50
K	10	0	0.00	0	0.00	2	0	0.00
L	146	0	0.00	0	0.00	5	0	0.00
M	71	0	0.00	0	0.00	2	0	0.00
SUMMARY	1889	17	0.90%	12	0.64%	169	11	6.51%

TABLE 5
COMPARISON OF PRE AND POST HACCP MILK PRODUCT AND WATER SAMPLE RESULTS

PLANT ID Code	Pre % Violative SPC	Post % Violative SPC	Pre % Violative Coliform	Post % Violative Coliform	Pre % Violative Water Result	Post % Violative Water Result
A	0.47	0.00	0.00	0.00	0.00	0.00
B	0.00	1.06	0.00	0.00	0.00	0.00
C	1.47	1.69	1.47	0.00	10.00	3.64
D	0.00	0.00	0.00	0.00	0.00	0.00
E	2.62	1.92	1.57	2.88	17.39	20.83
F	1.24	8.33	0.25	0.00	27.08	0.00
G	0.32	0.92	0.95	0.69	6.38	4.00
H	0.22	0.00	0.00	1.13	10.00	0.00
I	0.77	0.00	0.00	0.00	0.00	14.29
J	0.99	1.19	0.00	0.60	20.00	12.50
K	0.00	0.00	0.00	0.00	0.00	0.00
L	0.58	0.00	2.31	0.00	0.00	0.00
M	1.02	0.00	0.00	0.00	0.00	0.00
SUMMARY	0.75%	0.90%	0.55%	0.64%	12.07%	6.51%

Remarks:

1. Positive SPC in milk products increased .15% under the HACCP Pilot.
2. Positive Coli in milk products increased .09% under the HACCP Pilot.
3. Positive Coli in water decreased 5.56 % under the HACCP Pilot.

Conclusions:

Results of milk product and water sample testing when considered in total indicate that HACCP Pilot plants performed at least as well under the HACCP system as they did under the traditional system.

TABLE 6
Comparison of Pre-HACCP and Post-HACCP Surveys

Inspection Type	Plant by Code Letter	Inspection Date	1a	2a	3a	4b	5a	7a	8a	9a	10a	11a	13a	15aa	16a1a	16c1a	# marked
FDA Baseline	B	10/25/1999			x		x	x	X		x			x			6
FDA Post	B	1/17/2001											x	x			2
FDA Baseline	G	10/26/1999												x			1
FDA Post	G	1/31/2001				x					x	x		x		x	5
FDA Baseline	J	10/28/1999		x			x							x	x		4
FDA Post	J	1/3/2001		x							x						2
FDA Baseline	L	1/25/2002								x		x		x			3
FDA Post	L	12/18/2002	x							x				x			3

Remarks:

Two out of four HACCP plants achieved fewer marks on the Post-HACCP surveys when compared to their pre-HACCP baseline surveys.

One out of four HACCP plants received the same number of debits on the Post-HACCP survey when compared to their pre-HACCP baseline survey.

One out of four HACCP plants received an increased number of debits on the Post-HACCP survey when compared to their pre-HACCP baseline survey.

Conclusions:

Post-HACCP results indicate that three out of four plants improved or performed at the same level when compared to Pre-HACCP results.

Appendix IV.

Positive observations and comments from plant visits

Normally, observations from the Evaluation Team were comments identifying shortcomings in the implementation of the Phase II pilot by either the plant, state regulators or FDA Regional Milk Specialist. In order to provide a more balance view of the implementation of the Phase II HACCP pilot, observations that provide positive views have been grouped together and are presented below.

- ❑ Plant program met all requirements of the referenced NCIMS programs in the NCIMS HACCP pilot document, i.e. drug residue compliance, labeling of product, state regulatory samples, milk from listed sources, etc.

- ❑ The state resources to service the two HACCP pilot plants appear to be sufficient at this time, but the ability to provide updated HACCP training to staff is a problem.

- ❑ Two plant personnel participated in the Phase II NCIMS HACCP Training in Baltimore. The HACCP coordinator has a high level of training, experience and understanding of HACCP. All other plant personnel received GMP and general HACCP training annually and was well documented.

- ❑ Overall, the prerequisites were in relatively good shape and well documented. Generally, the records of prerequisite programs are some of the best documented of any plant we had visited.

- ❑ The records of the addition of boiler water compounds were very complete.

- ❑ The plant resources to maintain and keep the HACCP program current appear to be sufficient at this time based on management and corporate commitment.

- ❑ The plant seems to have its sanitation program highly organized.

- ❑ Participation assisted in transition for a new product.

- ❑ Aseptic process records were complete, accurate and properly documented. This is substantially improved from the last time.

- ❑ Allergen controls are sound and thorough.

- ❑ Great work instructions were used for training.

- ❑ HACCP certification has directly affected the plants ability to acquire new business.

- ❑ HACCP team divided into development and compliance teams, the evaluation team found this useful (all recent state audits had correction timeliness established.

- ❑ Charts have improved substantially since last visit.

- ❑ Plant plotted vacuum breakers on a chart and do a vacuum breaker, backflow preventer check monthly.
- ❑ Processing area is nice and clean and is improved since last time.
- ❑ Condition and cleanliness of food contact surfaces – every day swabs are conducted.
- ❑ Labeling storage and use of toxic compounds PP is excellent.
- ❑ Silo charts were excellent.
- ❑ The HACCP team was well chosen, HACCP involves everyone in plant and lab. The plant's view is that the HACCP team philosophically includes everyone in the plant.
- ❑ Three training sessions for all employees and weekly quality meetings include HACCP issues were scheduled at different times to include all shifts. Plant HACCP training program includes new employee training and annual refresher training. All training was well documented.
- ❑ Corrective action form (QS14904) was outstanding. One size fits all approach strongly supports uniformity but may not always be appropriate for minor corrections.
- ❑ Management commitment significant and noticeable. Contributed to the rapid development and implementation of the HACCP program. For this early in the program the HACCP system development was very mature.
- ❑ Appendix N monitoring and notification program was excellent.
- ❑ Appendix N regulatory and oversight program was excellent.
- ❑ Commitment to regulatory implementation of HACCP pilot by the state is very strong.
- ❑ State records were well organized and complete.
- ❑ All municipal and glycol water samples from 2000 till the present met PMO requirements.
- ❑ Finished product sample results prior to HACCP listing had limited number of high coliform counts for Past. Skim, with one high SPC count for nonfat dry milk and condensed skim. No high counts post-HACCP.
- ❑ The plant work instructions posted in laminated pages in areas throughout the production area clearly defines each operator's job. This includes pictures for labels of products to be dumped and cost.
- ❑ Temperature recorder in dry storage area where product ingredients stored.
- ❑ The case room has been significantly upgraded since the Evaluation Team's last time.

Also dump sinks for discarded product that flowed into processing was removed.

- ❑ Flow charts looked very good, complete and matched processes very closely. The internal consistency between the flow charts and HA made things very easy to follow.

- ❑ Hazard analysis very well done and include reclaim.

- ❑ Business including _____ and one other large account apparently were obtained as the result of NCIMS HACCP pilot participation. Plant manager stated that a HACCP program is a very necessary part of doing business and obtaining large account business. Also noted that _____ and _____ require HACCP and thought it would help with those accounts.

- ❑ Congratulate plant on separate PP for allergens and suggest that other pilot plants also do so.

- ❑ Separate programs for premise seemed to be related to excellent condition of premise. Suggest other plants also establish a separate premise PP.

- ❑ The plant has established prerequisites that are in addition to the eight required by the NCIMS HACCP pilot. This is a positive indication of their understanding of HACCP.

- ❑ Plant is physically well maintained.

- ❑ The new introduction and use of Process controls forms seemed to be an excellent addition to HACCP documentation system and are appropriate for prerequisite control.

- ❑ The state regulatory records were well organized, easy to review and complete. In addition, the extensive HACCP experience of the state HACCP auditors, listing personnel and administrator had a very positive impact on the implementation of the NCIMS HACCP pilot program.

- ❑ Like idea of check sheets in PP. Good example for other plants.

- ❑ List of documents included in HACCP program at end of HACCP plan very helpful.

- ❑ Table of contents for PP made reference very useful.

- ❑ Operating under HACCP not only enhanced their existing business but provided other opportunities.

- ❑ Participation in NCIMS HACCP program fulfilled requirement by brand names suppliers of _____, _____ and _____ for a HACCP plan.

- ❑ Encourage plant to take credit for the good work they are doing as the result to numerous prerequisite monitoring procedures and monitoring records in place that are not identified or listed as an integral part of their HACCP plant but serve as additional product safety safeguards.

- ❑ Flow diagrams very clear, comprehensive and easy to understand.
- ❑ Allergen control programs best we have seen. Separate packaging machines, separate scoops, separate rooms. Very good and comprehensive.
- ❑ Good automatic hand wash station at entrance to processing area.
- ❑ Stick floor pads good idea.
- ❑ Iodine beakers at packaging station and use of plastic gloves at same point good idea.
- ❑ They do not use water during processing and yogurt packaging in the processing room. Squirt iodine on floor every 15 minutes.
- ❑ Vat pasteurization charts are complete, comprehensive, organized and very good examples of industry work. Use of stamp very helpful to assure records are completely filled out.
- ❑ Pest control done by _____ and monitoring of pest control activity by the plant is adequate and documented.
- ❑ Including examples of many forms with the specific prerequisites was very helpful.
- ❑ COP logs have been improved three times demonstrating constant improvement and the fact that this program is living and breathing and at present time they are in excellent shape. Filler logs very good and include swab results crosschecked against filler logs.
- ❑ Level of respect enjoyed by HACCP team leader contributes significantly to the effectiveness of the HACCP system.
- ❑ Internal oversight and verification of HACCP records is significantly contributing the strength of the HACCP program and its comprehensiveness.
- ❑ Tanker seal program and recording of numbers on wash tags very good from security standpoint.
- ❑ HACCP team very effective in transferring knowledge and training about HACCP to production employees and supervisors.
- ❑ Packaging machine operators give list of activities during shift to oncoming shift operators and this improves communication.
- ❑ Finished product samples all within PMO limits for the past 2 years with no violations.
- ❑ State regulatory oversight doing very well in carrying out their role under the HACCP pilot.

- ❑ Plant reported that they obtained following benefits:
  - Identifies weak points in processing and control systems.
  - Provided access to a wider array of branded ingredients for top cup.

  - HACCP provides more control of processing system.

  - Staff better trained to assist in controlling processing system.

  - Pushes you to do what you know you should be doing.

  - HACCP has made production guys realize how important the things they do are and take more responsibility in sanitation instead of letting this fall back to third shift sanitation crew.

  - Training and additional documentation under HACCP help production staff to better understand records necessity and importance and result is more effort put into records. Also because records receive more review and checking, production staff makes more effort toward getting all necessary information on records.

  - HACCP appears to contribute to the "team" concept as opposed to a more individual approach before. This is especially noted in the shift changeover and information sharing between shifts.

- ❑ Plant's documentation and verification program was very complete and effective.

- ❑ Product labeling was adequate.

- ❑ The plant's ability to update and maintain the HACCP program has been enhanced by a stable workforce. Two years ago, the huge turnover of key personnel in the plant created training and implementation challenges that was partly the cause of pre-mature listing. The re-listing in December and the Evaluation team observations supported this improvement.

- ❑ The opportunity for plant and regulatory personnel to receive additional training as part of the Phase II transition has resulted in a strong understanding of the roles and responsibilities of the industry and regulators, contributing to good relationships and cooperative interaction. The FDA original uncertainty noted under Phase I by the state regulatory agency personnel, the FDA Regional Milk Specialist and the plant regarding their individual roles and the criteria for listing or delisting has significantly diminished.

- ❑ There was an overall feeling by plant, state and FDA personnel involved in the pilot that there was increased confidence in the safety versus the traditional NCIMS program.

- ❑ The Evaluation Team observed extremely strong support at the top levels of plant management which was instrumental in the successful development and implementation of the HACCP pilot program.

- ❑ Routine audit reports by the state were well done, complete with continuous follow-up to

monitor corrections.

- Corrections to problems noted to PP are generally appropriate and timely. The notice of what is needed is normally written on the PP worksheet or checklist. This is then provided to appropriate plant personnel for correction. No tracking or monitoring of correction for repeat occurrences. A central location for these records would be useful in performing effective root cause analysis. Done.

- Note: PP#6 talks about reconciliation of vitamin usage daily by weight. Most current reconciliation results on 108% and 112% which is excellent.

- The case washer with quaternary ammonia rinse.

- Use stainless steel air lines for air system and have a routine cleaning regime of about once per month.

- COP records are well documented and log used to track concentrations of CIP solution.

- Log for changing air filters is best ever seen because they check every air filter every day.

- Eggnog flow chart is very thorough.

- Overall, the PP are some of the best we have seen, in particular PP#2 on Cleaning and Sanitizing of equipment such as specifying visual inspection monitoring, chemical strength monitoring, frequency of cleaning, broken down by type of equipment, very detailed.